UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
This document relates to:	)	Case No. 17-md-2804
The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004 (N.D. Ohio)	)	Hon. Dan Aaron Polster
The County of Summit, Ohio, et al. v. Purdue Pharma L.P. et al., Case No. 18-OP-45090 (N.D. Ohio)	)	

REPORT OF KARL C. COLDER

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I. INTRODUCTION AND SUMMARY OF OPINIONS

A. Qualifications

1. Overview

In my 32 years with DEA, I gained extensive investigative and leadership experience while rising steadily through the ranks to become Special Agent in Charge of the Washington Field Division. After receiving a B.A. in Political Science and Social Relations/Criminal Justice from Cheyney University of Pennsylvania, I worked as an Alcohol and Drug Intake Counselor at the Philadelphia Diagnostic Rehabilitation Center from 1985 to 1986. I joined DEA in 1986 as a Special Agent—and later a Resident Agent in Charge—at various Field Division Offices. After gaining extensive investigative experience in these roles, I was reassigned to DEA Headquarters in 2002 to become an Inspector. I made this move to continue my climb up the ranks: DEA employees with supervisory responsibilities are required to do a tour at DEA Headquarters. I then became a Senior Inspector for the Office of Professional Responsibility for the Newark Field Office. In this role, I led all DEA administrative and criminal internal affairs operations for the Northeast region (New York, New Jersey, Pennsylvania, Delaware, and the New England states). In June 2005, I returned to active operations as Assistant Special Agent in Charge of the Philadelphia Field Division. I held this position until April 2009, when I took a promotion and returned to DEA Headquarters as Deputy Chief Inspector for the Office of Professional Responsibility, where I led internal investigations for the entire DEA. In 2013, I switched back to an operations role, becoming Special Agent in Charge for the Washington Field Division. As Special Agent in Charge, I directed all DEA operations throughout the states of Maryland, West Virginia, Virginia, and the District of Columbia. Upon retiring in 2018, I started Colder Allied Consulting, LLC, a consulting business in Virginia.

My Curriculum Vitae is attached as Exhibit A.

2. Pre-DEA Work Experience (1985-1986)

Coming out of college, I worked at the Diagnostic Rehabilitation Center in Philadelphia. As an Alcohol and Drug Intake Counselor, I conducted the intake process and coordinated the administration of treatment programs for individuals with alcohol or drug abuse issues. It was my job to ensure that treatment programs were administered as planned over the course of a patient's stay at the Center (usually one to two weeks). In this role, I frequently encountered individuals suffering from alcohol and drug abuse (*e.g.*, heroin, cocaine, and marijuana) issues.

3. Early DEA Operational Experience (1986-2002)

When I joined DEA in 1986, I worked in the Philadelphia Field Division. I quickly gained experience in a wide array of investigations. Street drugs—such as heroin, cocaine, and methamphetamine—occupied most of my time. I spent considerable time working as an undercover operative and a case agent to take down violent street gangs, who were flooding the streets with heroin and crack cocaine. And, since the ingredients needed to make methamphetamine were available off-the-shelf at this time, I recall facing major issues with mom-and-pop methamphetamine laboratories. Although I mainly focused on fighting illicit street drugs, I also gained first-hand experience investigating the diversion of medication—such as Percocet and Xanax—through doctor shopping and overprescribing.

In 1995, I moved to the Caribbean Field Division. There I spent most of my time working to intercept illicit street drugs (mainly heroin, cocaine, and marijuana) trafficked through the Caribbean Islands on their way from South America to the United States. To this end, I directed the initiation of the High Intensity Drug Trafficking Area Task Force in St. Croix, leading two Special Agents and three Virgin Islands Police Department Task Force Officers.

From 1998 to 2002, I took supervisory positions at the Dallas Field Division. Leading a group composed of DEA Special Agents and local law enforcement, I enforced drug laws and conducted interdiction investigations at the Dallas/Fort Worth International Airport. In 2001, I became the Resident Agent in Charge of the Fort Worth office. Although I recall heroin, methamphetamine, and cocaine being the main issues in our area at this time, as Resident Agent in Charge I also supervised three Diversion Investigators, who investigated suspected sources of diverted pharmaceuticals and chemicals.

4. Internal Investigation Experience (2002-2005; 2009-2012)

Although I didn't conduct operations during my two stints at the Office of Professional Responsibility, I gained a wide range of experience in these roles. As an example, while serving as Deputy Chief Inspector for DEA's Office of Professional Responsibility, I recall running the internal investigation into Carl Force—a DEA agent sentenced to 78 months in prison for scams that he committed while working undercover on DEA's investigation into Silk Road (a now defunct marketplace for illicit drugs accessible via the dark web).[1] During my time at the Office of Professional Responsibility, it was my job to provide guidance on proper DEA policy and procedures to everyone from trainees to senior DEA executives. Since I was investigating internal misconduct, and a violation could occur in any area, I needed to understand all aspects of DEA. For example, to investigate the potential misconduct of a Diversion Investigator, I needed to understand the expectations for such employees.

[1] *See* O'Neill, Patrick, *DEA agent arrested for stealing Silk Road bitcoins also orchestrated murder-for-hire scheme*, The Daily Dot (Mar. 30, 2015), *available at* https://www.dailydot.com/crime/carl-force-silk-road-murder-for-hire/; Mullen, Joe, *Corrupt Silk Road agent Carl Force sentenced to 78 months*, Arstechnica.com (Oct. 19, 2015), *available at* https://arstechnica.com/tech-policy/2015/10/corrupt-silk-road-agent-carl-force-sentenced-to-78-months/; Higgins, Stan, *Rogue Silk Road Agent Carl Force Jailed for 78 months*, Coindesk (Oct. 21, 2015), *available at* https://www.coindesk.com/rogue-silk-road-agent-carl-force-jailed-for-78-months.

5. Later DEA Operational Experience (2005-2009; 2013-2018)

As Assistant Special Agent in Charge of the Philadelphia Field Division, I assisted the Special Agent in Charge in developing division priorities and programs. I occupied a leadership role, taking charge of one of the first Tactical Diversion Squads (which were made up of Diversion Investigators and enforcement officers) in the DEA and leading other enforcement groups. While at the Philadelphia office, I also took part in Operation Cyber Chase—an operation that targeted rogue internet pharmacies.[2] Although I gained extensive experience in pharmaceutical diversion investigations during this time, our primary focus was illicit street drugs (such as heroin and cocaine) and their links to regional, national, and international drug trafficking organizations. I recall dealing with the emergence of illicit fentanyl during this time as well.

In my role as Special Agent in Charge of the Washington Field Division, I ran all DEA operations throughout Maryland, West Virginia, Virginia, and the District of Columbia—a vast region at the epicenter of the opioid abuse crisis. I was responsible for developing my division's priorities, strategies, policies, and programs. I oversaw more than 500 personnel, including five Assistant Special Agents in Charge, a Diversion Control Program Manager, and a Field Intelligence Manager. It was my job to develop strategic and performance plans for the employees under my control, and to ensure that they adhered to these plans. I also managed the Washington Field Division's Diversion Program, under which we registered, monitored, and audited medical practitioners, pharmacists, pharmaceutical manufacturers, and pharmaceutical distributors. As part of this responsibility, I was involved in settlements with pharmacies and pharmaceutical distributors related to DEA investigations into their suspicious order monitoring systems.[3] It was

[2] *See* Press Release, *International Internet Drug Ring Shattered*, DEA (Apr. 20, 2005), *available at* https://www.dea.gov/sites/default/files/pubs/pressrel/pr042005.html.

[3] *See* Press Release, *Washington: Pennsylvania Pharmaceutical Wholesaler Value Drug, Inc. to Pay $4,000,000 in Settlement*, DEA (June 25, 2014), *available at* https://www.dea.gov/press-releases/2014/06/25/pennsylvania-

also my job to manage the Washington Field Division's budget. In doing so, I regularly drafted proposals outlining how DEA should use its limited resources to fight the opioid abuse crisis in my region. Although I occupied a senior leadership position, I took pride in engaging with constituents of the communities I served, which allowed me to better understand their problems and work together to develop solutions. For example, as part of the DEA 360 Strategy, I engaged with community leaders, registrants, and law enforcement in West Virginia to identify strategies to fight the opioid abuse crisis plaguing that state.

6. Education

Prior to joining DEA, I received a B.A. in Political Science in 1983 and a B.A. in Social Relations/Criminal Justice in 1984, both from Cheyney University of Pennsylvania. In 2009, I earned a Master's Degree in Human Resources Development and Training from Seton Hall University.

7. Professional and Community Affiliations

I hold (or formerly held) several positions in professional and community organizations, including the following:

- National Association of Black Narcotics Agents (*Former National President*)
- Metropolitan Washington Council of Governments Substance Dependency Program (*Chairman of Executive Planning Committee*)
- Baltimore/Washington and Appalachia High Intensity Drug Trafficking Area Task Force (*Executive Committee Chairman*)
- Episcopal Church Province 3 Opioid Abuse Task Force (*Co-Chair*)

pharmaceutical-wholesaler-value-drug-inc-pay-4000000; Press Release, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Justice Department Documents and Publications (Dec. 23, 2016), *available at* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act; *Feds: McKesson agrees to pay $150M in pill shipment case*, U.S. News & World Report (Jan. 17, 2017), *available at* https://www.usnews.com/news/business/articles/2017-01-17/feds-mckesson-agrees-to-pay-150m-in-pill-shipment-case.

B. Retention and Scope of Work

I understand that Allergan Finance, LLC, Allergan plc, Allergan Sales, LLC, Allergan USA, Inc., Actavis Pharma, Inc., Actavis LLC, Watson Laboratories, Inc., Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and others, have been sued by a number of plaintiffs in *In re: National Prescription Opiate Litigation* (MDL No. 2804). I have been retained to provide expert opinions on behalf of Allergan Finance, LLC, as well as Teva and Actavis Generics defendants, on the following topics:

- Knowledge of the DEA's interpretation and enforcement of 21 U.S.C. § 823 and 21 C.F.R. §1301.74;
- Knowledge of communications with DEA registrants, generally, whether written or oral, regarding their obligations under 21 C.F.R. §1301.74;
- DEA practices and procedures relating to the use of ARCOS data to combat diversion;
- Knowledge of the DEA's efforts to combat illicit opioid markets and illicit opioids; and
- Knowledge of DEA initiatives and work performed to combat the opioid abuse crisis, including community engagement, diversion training, and enforcement.

I am being compensated at my usual rate of $300 per hour, plus reasonable expenses. My compensation is in no way based on the outcome of this litigation or on the content of my opinions or testimony.

C. Introduction

DEA's mission is to "enforce the controlled substances laws and regulations of the United States." [4] The Controlled Substances Act ("CSA")—which is enforced and administered principally by DEA—uses the concept of registration to bestow legal authority to handle controlled substances. [5] Under Section 822 of the CSA, manufacturers and distributors of controlled substances are required to register with DEA: "Every person who manufactures or distributes any controlled substance, or who proposes to engage in the manufacture or distribution of any

[4] DEA Website: Mission Statement, *available at* https://www.dea.gov/mission.

[5] *See* 21 U.S.C. § 801 *et. seq.*

controlled substance or list I chemical shall obtain annually a registration . . ."[6] Section 823 of the CSA sets forth factors to be considered by DEA prior to issuing a registration, which includes, among other things, that the registrant maintain "effective controls against diversion . . ."[7] If DEA determines that a registrant is not in compliance with the CSA, DEA has authority to revoke or suspend its registration, pursue administrative enforcement actions (*e.g.*, Letter of Admonition, Informal Administrative Hearing, Order to Show Cause), and to seek civil fines or criminal penalties in federal district court.[8]

DEA is also tasked with setting quotas—both in the aggregate and at the individual manufacturer level—for controlled substances.[9] By including the quota system in the CSA, Congress intended to "reduce or eliminate diversion."[10] Indeed, the purpose of quotas "are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion."[11]

D. Summary of Opinions

Based on my analysis—which has been informed by my 32 years of experience at DEA and my review of the materials cited throughout this report and in Exhibit B—I have formed the

[6] *See* 21 U.S.C. § 822(a)(1).
[7] *See* 21 U.S.C. § 823(a)(1).
[8] *See* 21 U.S.C. § 801 *et. seq;* Rubin, Paul D., et al, "*Chapter 23: Compliance with DEA Controlled Substance Requirements*," PLI, Health Care Mergers and Acquisitions Answer Book (2018); Gilbert, John A. & Houchk, Larry K., "*Chapter 17: Controlled Substances*," FDA Deskbook: A Compliance and Enforcement Guide (2018).
[9] *See* 21 U.S.C. § 826; 21 C.F.R. Part 1303.
[10] *See* Press Release, *DEA Reduces Amount Of Opioid Controlled Substances To Be Manufactured In 2017*, DEA (Oct. 4, 2016), *available at* https://www.dea.gov/press-releases/2016/10/04/dea-reduces-amount-opioid-controlled-substances-be-manufactured-2017.
[11] *Id.; see also* Apr. 11, 2019 Dep. of Stacy Harper-Avilla at 47:9-13 ("Q. What is the -- is it fair to say that one of the purposes of granting procurement quota is to ensure an adequate and uninterrupted supply of medications? A. It is one purpose.").

opinions described in this report to a reasonable degree of certainty. In general, those opinions include the following:

- DEA's suspicious order monitoring regulation and guidance is and has been vague and subjective, leaving registrants with significant discretion in creating their suspicious order monitoring systems.
- DEA did not provide meaningful guidance to registrants seeking more information on how to comply with their suspicious order monitoring obligations, leaving interpretation to the discretion of individual registrants.
- The claims of James E. Rafalski and Dr. Seth B. Whitelaw (two individuals retained by Track One Plaintiffs) that a compliant suspicious order monitoring system requires specific components has no basis in regulation and is inconsistent with DEA practice.
- If a company received no notification, action, or warning from DEA related to their suspicious order monitoring system even after regular audits, the registrant could expect that DEA did not find any violations of the relevant suspicious order monitoring laws and regulations.
- DEA's failure to allocate sufficient resources to the geographic areas in greatest need contributed to the growth of the opioid abuse crisis.
- DEA could have better responded to the opioid abuse crisis by allocating its resources in a more balanced manner across enforcement, diversion control, and community engagement.
- DEA did not effectively use its exclusive access to complete, aggregated ARCOS data to combat the opioid abuse crisis.
- DEA did not effectively utilize suspicious order reports submitted by registrants to identify targets contributing to the growth of the opioid abuse crisis.
- Illegal street opioids, most notably heroin and fentanyl, were and are DEA's primary focus during the opioid abuse crisis.
- Illicit sources for prescription opioids—such as pills mills, internet pharmacies, and doctor shopping—were and are a major cause of the opioid abuse crisis.[12]

II. DEA'S SUSPICIOUS ORDER MONITORING REGULATION AND RELATED GUIDANCE IS VAGUE AND SUBJECTIVE, LEAVING REGISTRANTS WITH SIGNIFICANT DISCRETION IN CREATING A COMPLIANT SUSPICIOUS ORDER MONITORING SYSTEM.

Among other things, the CSA creates a closed regulatory system that establishes strict controls over the manufacture, distribution, dispensing, or possession of controlled substances.[13]

[12] I reserve the right to amend or supplement this report based on any additional information that is brought to my attention, including, but not limited to, information from documents, expert reports, or testimony. If called to testify, I may use summaries and demonstratives (prepared and disclosed pursuant to the Court's scheduling orders) to assist my testimony.

[13] *See* 21 U.S.C. § 801 *et. seq.*

A person or entity must register with the DEA in order to become a part of this closed system.[14] The Attorney General is granted the authority to register an applicant to manufacture Schedule I or II controlled substances "if he determines that such registration is consistent with the public interest[.]"[15] In determining the public interest, the statute lists several factors to be considered, including:

> "maintenance of effective controls against diversion of particular controlled substances … into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes[.]"[16]

The implementing federal regulation that addresses suspicious order monitoring has remained the same since it was promulgated in 1971:

> "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[17]

The DEA has issued some guidance about how to interpret the suspicious order monitoring regulation through formal letters provided to registrants,[18] presentations to individual companies at distributor briefings,[19] and presentations to registrants at industry conferences.[20] The DEA also provided guidance to Diversion Investigators about how to apply the CSA and federal

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14 *See* 21 U.S.C. § 822.
15 *See* 21 U.S.C. § 823(a).
16 *See* 21 U.S.C. § 823(a)(1).
17 *See* 21 C.F.R. § 1301.74(b).
18 *See, e.g.*, ALLERGAN_MDL_02467796 (the "2006 Dear Registrant Letter"); ALLERGAN_MDL_02187202 (the "2007 Dear Registrant Letter").
19 *See, e.g.*, US-DEA-00000143; US-DEA-00000588; US-DEA-00000214; US-DEA-00000367; US-DEA-00000368; US-DEA-00000378; US-DEA-00000386; US-DEA-00000404; US-DEA-00000469; US-DEA-00000933; US-DEA-00001043.
20 *See, e.g.*, DEA Presentation: *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conferences (2013), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/arnold.pdf; and DEA Presentation: *Manufacturer Trends & Updates*, Manufacturer Conference (2015), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2015/prevoznik.pdf.

regulation through the Diversion Investigators' Manual.[21] Additionally, the DEA provided guidance to its Diversion Program Managers, Group Supervisors, and Senior Diversion Investigators through OD Policy Letters issued by the DEA Headquarters Office of Diversion Control.[22]

In my role as Special Agent in Charge, I managed the overall functions of the Washington Field Division, including its Diversion Control Program, under which pharmaceutical manufacturers, pharmacists, and medical practitioners are registered, monitored, and audited. I oversaw our Diversion Control Program through the day-to-day management of our Diversion Program Manager. I was also involved in settlements with distributors and pharmacies related to suspicious order monitoring.[23]

In reaching the opinions set forth below related to suspicious order monitoring, I relied on DEA's regulations and general guidance letters, as well as my own experience (described in greater detail in Section I(A) and Exhibit A).

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[21] *See, e.g.*, CAH_MDL2804_02203353 at -3355 *et. seq.* (1996); CAH_MDL2804_02145395 at -5399 *et. seq.* (2011).

[22] *See, e.g.*, US-DEA-00005839; US-DEA-00005841; US-DEA-00005925; US-DEA-00005928; US-DEA-00005918; US-DEA-00005921; US-DEA-00005911; US-DEA-00005914; US-DEA-00005949; US-DEA-00005952; CAH_MDL2804_00958601; ABDCMDL00269679.

[23] *See* Press Release, *Washington: Pennsylvania Pharmaceutical Wholesaler Value Drug, Inc. to Pay $4,000,000 in Settlement*, DEA (June 25, 2014) *available at* https://www.dea.gov/press-releases/2014/06/25/pennsylvania-pharmaceutical-wholesaler-value-drug-inc-pay-4000000; Press Release, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Justice Department Documents and Publications (Dec. 23, 2016), *available at* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act; *Feds: McKesson agrees to pay $150M in pill shipment case*, U.S. News & World Report (Jan. 17, 2017), *available at* https://www.usnews.com/news/business/articles/2017-01-17/feds-mckesson-agrees-to-pay-150m-in-pill-shipment-case.

A. The DEA's suspicious order monitoring regulation and policies have been and remain vague.

Based on my experience, DEA's suspicious order monitoring regulation and policies were vague, leaving registrants with discretion in developing their own suspicious order monitoring programs.

1. Identifying potentially suspicious orders

The federal regulation states that the registrant must "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[24] The only codified information about how to identify "suspicious orders" is that "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[25] This definition hardly provides any clarity at all. What constitutes an order of unusual size? How are registrants to establish a normal pattern? And what kind of deviation from that pattern is considered substantial? What level of frequency is considered unusual?

Based on my experience at DEA, these terms were never clarified or explained in greater detail. Registrants were left to determine the meaning of these terms on their own and to report what *they* considered unusual. The effective design of a suspicious order monitoring system was subjective and left to the discretion of the registrant.[26] While the DEA provided several

[24] 21 C.F.R. § 1301.74(b).

[25] *See id.*

[26] *See* Feb. 28, 2019 Dep. of Kyle Wright at 71:1-8 (stating that DEA "did not dictate the criteria … for identifying excessive purchases"); *id.* at 195:22-196:18 (deciding if a volume increase is enough to make an order suspicious is "a judgment call by the manufacturer based upon their data");

See Mar. 15, 2019 Dep. of Demetra Ashley at 89:5-22 (stating that designing a suspicious order monitoring system is within the distributors' discretion, and that whether the system is effective is a subjective determination); *id.* at 246:4-247:1 (whether an order meets suspicious criteria varies from situation to situation); *id.* at 26:16-22 ("Q: Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A: No. Q: Does the regulation provide guidance as to what constitutes an order of unusual frequency? A: No."); *id.* at 147:1-7 ("Q: … So how much of a deviation would make it unusual? A: That would be determined by the distributor or the manufacturer. Q: So is there any threshold for determining whether a deviation is unusual? A: Not that the DEA sets, no."); *id.* at 88:2-10 ("Q: To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? … A: To my knowledge, there is not.");

suggestions and ideas about factors a registrant might take into consideration when designing a system, they required few. Orders can be reviewed through an automated system, or manually.[27] There is no list of characteristics, capabilities, or functions that a compliant suspicious order monitoring system must have, nor is there any requirement that a registrant must have written policies and procedures with respect to suspicious order monitoring.[28] Registrants largely have been left to figure out for themselves what would work best for their company, and to tweak their systems over time to account for new patterns, technologies, customers, or trends.[29]

Indeed, as noted by the Energy and Commerce Committee, "[n]either federal regulations nor the DEA . . . require distributors to use any particular method or system to flag those orders. As a result, individual distributors have designed and implemented their own unique detection systems to flag suspicious orders . . ." [30] Even Plaintiffs' expert James E. Rafalski has

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See Apr. 17, 2019 Dep. of Thomas Prevoznik at 179:22-180:11 ("Q: Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A: Yes. Q: And there's no single feature that makes a suspicious order monitoring system compliant, correct? A: Correct. Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct."); *Id*. at 183:1-12 ("Q: … [Y]ou and I looking at the same data, sometimes, not always, may come to different conclusions, as to whether an order is suspicious. Is that possible? … A: That is possible.");

See Apr. 26, 2019 Dep. of Joseph Rannazzisi at 120:1-4 (stating that "[i]t's up to the -- the distributor or the manufacturer, distributor to make a decision what information they will use to determine suspicious orders.").

[27] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 180:12-15 ("Q: Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A: No, it doesn't matter.");

See Mar. 15, 2019 Dep. of Demetra Ashley at 88:11-89:4 ("Q: To your knowledge, does a legally compliant system need to be automated? A: No, it does not. Q: Does it need to be manual, i.e., the opposite of automated? … A: It's not specific. There's no direction on how to do it. Q: Are there particular methods of investigation that are required in order for a system to be legally compliant? A: Yes. Q: What are they? A: The method would be to -- as it's outlined in the regulation, to take a look at the order, make a determination if it's deviating from what's usual. I mean, how you do it, it can be manual or automatic, but it's just that it needs to be done.").

[28] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 358:21-359:1 ("Q: Does it say anywhere in the relevant regulations that registrants are required to have a written policy with respect to suspicious order monitoring? A: No.").

[29] *See id*. at 180:7-10 ("Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct.").

See Mar. 15, 2019 Dep. of Demetra Ashley at 310:8-9 ("Q: Now, I'm correct in stating that the statute and reg does not tell them how to do their job, the registrants, correct? A: That's correct."); *id*. at 286:22-287:1 ("Q: You didn't tell them how to make their suspicious order monitoring system, did you? … A: We did not tell them how to make their suspicious order monitoring system.").

[30] *See Red Flags and Warning Signs Ignored: Opioid Distribution and Enforcement Concerns in West Virginia*, Energy & Commerce Committee Report, U.S. House of Representatives (Dec. 19, 2018) ("Dec. 19, 2018 Energy & Commerce Committee Report") at 180, *available at* https://republicans-energycommerce.house.gov/wp-content/uploads/2018/12/Opioid-Distribution-Report-FinalREV.pdf.

acknowledged that "Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious."[31] And this ambiguity is widely recognized by DEA employees, and even the DEA itself.[32] Accordingly, the compliance processes, metrics, and/or algorithms applied in the expert reports of Craig McCann and Lacey Keller are not the only steps that a company could have used to identify potentially suspicious orders.

The DEA has provided limited guidance to manufacturers about how to comply with the suspicious order monitoring regulation.[33] In fact, the 2007 Dear Registrant letter from Joseph Rannazzisi was the *only* written industry-wide guidance provided by DEA to manufacturers.[34] The

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[31] *See* Apr. 15, 2019 Expert Report of James Rafalski at 12-13.

[32] *See* Feb. 28, 2019 Dep. of Kyle Wright at 71:1-8 (stating that DEA "did not dictate the criteria … for identifying excessive purchases"); *id.* at 195:22-196:18 (deciding if a volume increase is enough to make an order suspicious is "a judgment call by the manufacturer based upon their data");

See Mar. 15, 2019 Dep. of Demetra Ashley at 89:5-22 (stating that designing a suspicious order monitoring system is within the distributors' discretion, and that whether the system is effective is a subjective determination); *id.* at 246:4-247:1 (whether an order meets suspicious criteria varies from situation to situation); *id.* at 26:16-22 ("Q: Does the regulation tell -- provide guidance as to what constitutes an order of unusual size? A: No. Q: Does the regulation provide guidance as to what constitutes an order of unusual frequency? A: No."); *id.* at 147:1-7 ("Q: So how much of a deviation would make it unusual? A: That would be determined by the distributor or the manufacturer. Q: So is there any threshold for determining whether a deviation is unusual? A: Not that the DEA sets, no."); *id.* at 88:2-10 ("Q: To your knowledge, is there a particular formula or algorithm that is required for a legally compliant system? … A: To my knowledge, there is not.");

See Apr. 17, 2019 Dep. of Thomas Prevoznik at 179:22-180:11 ("Q: Now, does the DEA agree that there's more than one way to design and operate a system that can identify and report suspicious orders? A: Yes. Q: And there's no single feature that makes a suspicious order monitoring system compliant, correct? A: Correct. Q: And the DEA leaves it up to the registrant to design a system that works with its own business model and customer base, correct? A: Correct."); *id.* at 183:1-12 ("Q: [Y]ou and I looking at the same data, sometimes, not always, may come to different conclusions as to whether an order is suspicious. Is that possible? … A: That is possible.");

See Apr. 26, 2019 Dep. of Joseph Rannazzisi at 120:1-4 (stating that "[i]t's up to the -- the distributor or the manufacturer, distributor to make a decision what information they will use to determine suspicious orders.").

[33] *See* Feb. 28, 2019 Dep. of Kyle Wright at 192:1-6 ("Q: During the time period that you were involved in the distributor initiatives, are you aware of any guidance the DEA provided to manufacturer registrant regarding Suspicious Order Monitoring? A: Specifically, no."); *id*. at 193:5-10 ("Q: As you sit here today, can you remember any guidance whatsoever that the DEA provided to manufacturer registrants regarding their obligations under the Suspicious Order Monitoring regulation? A: No.").

[34] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 305:17-22 ("Q: Since 2007 and the letter from Joe Rannazzisi, has the DEA provided manufacturers with any further written guidance regarding the obligation to monitor suspicious

2007 letter addressed three key points with respect to the design and operation of a system to identify potentially suspicious orders.

First, the letter stated that the factors defining a suspicious order listed in the federal regulation ("orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency") were "disjunctive" and "not all-inclusive."[35] In other words, an order could be considered suspicious even if it was only an order of unusual size. Further, the three factors listed in the regulation were not the only factors that could make an order suspicious.

Second, the DEA suggested an expanded reading of the word 'pattern,' indicating that it depends "not only the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry."[36] To my knowledge, this was the first time that the DEA ever suggested that registrants monitor such patterns, and the DEA provided no guidance or direction on how to do so or what kinds of factors to consider. Moreover, guidance letters are intended to provide suggestions only, and they do not create mandatory rules or requirements for compliance.[37] Discretion was always left up to the registrant to design and operate a system that worked with its own unique business.

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orders? A: No."); *id*. at 285:16-21 ("Q: And aside from those 2006 and 2007 letters from Joe Rannazzisi, was there any other written guidance provided to manufacturers regarding how to identify a suspicious order? A: No."); *id*. at 178:19-179:9 ("Q: So essentially there was no industrywide guidance that was provided in 2008 or forward as to how to design or implement suspicious order monitoring systems, true? … A: Nationwide, correct. Q: Instead, one-off guidance was perhaps provided in the context of individual distributor meetings, correct? A: Yes. Along with the MOAs and the settlements that were done.").

35 *See* ALLERGAN_MDL_02187202.

36 *See id.*

37 *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 370:15-23 (stating "I don't understand how guidance is a new requirement. Rulemaking would make a new requirement. … guidance is not going to create a new rule."); *id*. at 373:16-18 ("guidance is not imposing new requirements. It's not -- it's not imposing them."); *id*. at 374:5-9 ("Q: And guidance should not impose new requirements, correct? A: I don't believe guidance is -- any guidance is imposing new requirements.").

See US-DEA-00005914 (stating that "DEA is unable to require anything more" concerning a suspicious order monitoring matter "than what is stated in the Controlled Substances Act and its implementing regulations.").

Third, the 2007 Dear Registrant Letter to manufacturers only gave an example of a suspicious order monitoring system that was *not* sufficient. The letter says:

> "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient."[38]

In my opinion, this example illustrated two points. First, the DEA expected some element of human investigation and analysis to go into the determination of whether an order is suspicious, and expected some level of flexibility; a "rigid formula" was not enough. In other words, the DEA knew from its own experience investigating diversion that identifying a large number of pills or bottles sold was only the start of the inquiry. Obtaining context about the customer and the order is necessary to understand whether that number of pills or bottles truly amounted to a "suspicious order."[39]

Second, the DEA's sole example of an insufficient system was one that uses "*only*" one data point—the total amount of controlled substances ordered during one month vs. the previous month. To *only* perform a numerical analysis from one month to the next and nothing else would be insufficient, according to the letter. But this example says nothing of a system that compares current orders to several months or a year's worth of purchase history, nor a system that incorporates other factors, data points, or human investigation into the ultimate determination of what is suspicious. In my opinion, numbers can be a valuable starting point, used to set a threshold

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[38] US-DEA-00001767 at 1772.

[39] In this way, I agree with Plaintiffs' expert Seth B. Whitelaw when he says that "the establishment of thresholds … is an effective way to identify, but not to confirm, suspicious orders" and that compliance programs "must still rely on experienced human resources, with intelligence and common sense, to review and understand the context surrounding each outlier or anomaly and then to apply the correct, balanced solution. Thus, in the end, good compliance comes down to experienced people making good choices." *See* Apr. 15, 2019 Expert Report of Dr. Seth B. Whitelaw at 33, 25.

above which further investigation is warranted. As long as a rigidly defined, single-factor formula is not doing all of the work, then the registrant is not running afoul of the guidance provided in this letter.

Finally, the DEA asserted in its letter that it would not "approve or otherwise endorse any specific system for reporting suspicious orders."[40] Indeed, in its letter, the DEA stated, "[p]ast communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."[41]

2. Investigating potentially suspicious orders

In addition to identifying potentially suspicious orders, the DEA expected registrants to conduct some investigation into these orders to determine whether they were legitimate or truly suspicious. This is because orders of unusual size, pattern, or frequency are not always suspicious.[42] There are a wide array of legitimate reasons why a customer might make an order of unusual size, pattern, or frequency that is not indicative of diversion. Because orders flagged by an algorithm may be (and often are) legitimate, the due diligence process is necessary to determine which orders are truly suspicious.[43]

Like the system used to identify these orders, this due diligence process could take many forms and the specific method of investigation was left to the discretion of the registrant. The CSA

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[40] ALLERGAN_MDL_02187202.

[41] *Id*.

[42] *See* Mar. 15, 2019 Dep. of Demetra Ashley at 147:8-11 ("Q: Based on your experience, would you agree that there might be situations where an order is of an unusual size, but the order is not suspicious? A: Yes."); *id*. at 150:13-18 ("Q: Do you agree that there might be situations where an order deviates substantially from a normal pattern and is not suspicious? … A: Yeah, that could happen."); *id*. at 150:24-151:2 ("Q: In your experience, would you agree that there might be situations when an order of unusual frequency is not suspicious? A: Yes, I would agree to that.").

[43] McCann and Keller did not conduct any due diligence into any order flagged by their compliance metrics or algorithms; thus, they are very likely to be overstating the number of orders flagged by those algorithms that were truly suspicious.

and implementing regulations are silent as to the parameters that governed this diligence. Similarly, the DEA did not require any particular form of documentation of the due diligence process, nor did it require that a registrant keep such documentation at all.[44]

The DEA's September 27, 2006 letter, sent only to distributors but not manufacturers, discussed the "statutory obligation to exercise due diligence," and stated that "a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances."[45] But when it comes to "suspicious circumstances," the letter did not provide any hard and fast requirements about what sorts of circumstances must be analyzed during the "due diligence" process. Rather, it provided a number of suggestions—circumstances and characteristics that a distributor "may wish to" consider, which "may be indicative of diversion."[46] The four circumstances listed were presented as typical characteristics of pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose. No such guidance about due diligence into distributors—who are more typically

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[44] *See* Feb. 28, 2019 Dep. of Kyle Wright at 143:2-12 ("Q: And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? … A: No."); *id*. at 496:23-497:4 ("Q: And it is the documentation of -- whatever due diligence is done by a company, that may be a best practice, but it is not required by statute or regulation, correct?" … A: Yes, ma'am.").

See Mar. 15, 2019 Dep. of Demetra Ashley at 252:5-18 ("Q: Is how the records are kept in connection with suspicious orders something that's left to the discretion of distributors …? A: How the records are kept are left to the discretion of the distributor, yes. Q: Is the documentation of a distributor suspicious order monitoring system how it's -- how it is set up and how it's implemented also something that is in the discretion of the distributors? A: Yes.").

See May 17, 2019 Dep. of Thomas Prevoznik 1212:13-19 ("Q: And I believe that you indicated that there was not any sort of requirement by the DEA of the maintenance of due diligence files, correct? … A: Yes."); *id*. at 1216:8-12 ("Q: Coming back to the concept of due diligence, the DEA has not issued any guidance specifying how long a registrant must hold on to due diligence, correct? A: Correct."); *id*. at 1218:17-1219:10 ("Q: The DEA has certainly never issued any kind of guidance indicating that a registrant must hold on to due diligence files for 15 years, correct? A: Yes, the only guidance I know is it's two years, two years for recordkeeping for the registrant. Q: Okay. A: For us. Q: But there's no requirement that a due diligence file even be maintained, correct? A: Correct. Q: So the two-year rule does not apply to any due diligence files, per se, correct? A: Correct.") *id*. at 1220:20-1221:7 ("Q: Is there any sort of requirement, either by the DEA or by the registrant, to hold on to an actual suspicious order being reported to the DEA? … A: No. Q: Has the DEA issued any sort of guidance indicating how long a suspicious order that's been reported must be maintained? A: No.").

[45] *See* ALLERGAN_MDL_02467796.

[46] *See id*.

customers of manufacturers—was included in the 2007 Dear Registrant Letter sent to manufacturers, which was described above.

3. Reporting suspicious orders

In addition to requiring registrants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," the federal regulation states that a "registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."[47]

Registrants could report suspicious orders in a variety of ways, whether by email, phone, fax, or letter.[48] The regulation is silent as to the method of reporting, what format the report should take, and what level of detail the report should contain.[49]

B. DEA refused to provide meaningful guidance to registrants seeking clarification on how to comply with their suspicious order monitoring requirements, leaving interpretation to the discretion of individual registrants.

The nature and importance of suspicious order monitoring makes the DEA's failure to provide a clear regulation problematic. The ideal suspicious order monitoring program is neither overinclusive nor underinclusive, and manages to achieve two conflicting goals. On the one hand, it is important that suspicious order monitoring programs detect illegitimate orders of controlled substances; on the other hand, it is also vital that they don't prevent patients from receiving the medication they need. In the words of the U.S. Government Accountability Office ("GAO"),

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[47] 21 C.F.R. § 1301.74(b).

[48] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 51:15-23 ("Q: And those suspicious orders are reported to the field, as a general matter, electronically; is that right? A: No. I mean they could come in e-mail, it could be attached to an e-mail, like a spreadsheet. They come in as -- I know it's hard to believe, but people still fax. It comes in snail mail, various different forms.");

See May 17, 2019 Dep. of Thomas Prevoznik at 1227:25-1228:5 (confirming that suspicious orders that were reported for controlled substances sometimes got phoned in).

[49] *See* Mar. 15, 2019 Dep. of Demetra Ashley at 27:14-19 ("Q: Does the regulation say what type of reports are supposed to be submitted? A: The type? Q: Well, what they're supposed to look like, what's supposed to be in them. A: The regulation does not say that.").

"[c]ontrolled substance diversion poses a unique challenge because of the need to balance prevention, education, and enforcement with the need for legitimate access."[50]

DEA recognized the importance of these competing objectives—according to its own website, "[t]he mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."[51] Despite this awareness, DEA failed to provide registrants with a clear suspicious order monitoring regulation.

Based upon my experience and my review of testimony in this case, subject to vague suspicious order monitoring requirements, the vast majority of registrants diligently strived to comply.[52] To this end, many registrants sought additional guidance from DEA about how to design or operate a compliant suspicious order monitoring system or how to most effectively prevent diversion.[53]

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[50] *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results*, United States Government Accountability Office (August 2011) ("2011 GAO Report"), *available at* https://www.gao.gov/products/GAO-11-744.

[51] *See* DEA Website: Diversion Control Division, *available at* https://www.dea.gov/diversion-control-division ; *see also* Mar. 15, 2019 Dep. of Demetra Ashley at 234:2-8 ("Q: Will you agree, based on your 35 years of experience at the DEA, that what the Office of Diversion Control is attempting to do is, on one hand, minimize the amount of diversion that occurs while at the same time ensuring that folks who need opioids or other controlled substances can get them? A: I agree with that."); *id.* at 197:22-25 ("Part of the mission of the Office of Diversion Control is to ensure an adequate supply of controlled substances are available to meet legitimate medical need.").

[52] *See id*. at 329:14-22 ("Q. In your, frankly, remarkable career of rising from a secretary all the way up to an executive at DEA, isn't it the case, Ms. Ashley, that the vast majority of registrants with whom you dealt were trying to comply with the CSA and the implementing regs? . . . A: I agree with that, yes.").

[53] *See, e.g.*, US-DEA-00005928 at 5930 (letter to DEA from supervisor of pharmacy); US-DEA-00005921 at -5923 (letter to DEA from owner of independent pharmacy); US-DEA-00005914 at -5916 (letter to DEA from National Community Pharmacist Association); US-DEA-00005952 at -5954 (letter to DEA from Maryland Board of Pharmacy); US-DEA-00006056 (email reflecting that a registrant "is asking (maybe even begging) for direction as to how to comply"); US-DEA-00008565 (June 1, 2011 questions submitted by the Healthcare Distribution Management Association to DEA re suspicious order monitoring requirements); US-DEA-00008577 (July 31, 2013 questions submitted by the Healthcare Distribution Management Association to DEA re suspicious order monitoring requirements).

DEA recognized the importance of providing guidance to registrants. In his testimony before the Energy and Commerce Committee, Joseph Rannazzisi, former Deputy Assistant Administrator of the Office of Diversion Control, claimed that "DEA conducts a number of outreach initiatives intended to educate registrants on their responsibilities, discuss suspicious order monitoring, and respond to other registrant inquiries." [54] Testifying before the United States Senate Caucus on International Narcotics Control, Rannazzisi pointed to the Distributor Initiative Program—established in 2005 to help "educate registrants on maintaining effective controls against diversion, and monitoring for and reporting suspicious orders"—as an example of DEA's engagement with industry.[55]

DEA witnesses have also expressed their belief in the importance of communicating with registrants and providing clear guidance on how to comply with their obligations.[56] I agree with Demetra Ashley, who testified about the need for DEA to engage with registrants in order to achieve its goals: "[i]t's part of DEA's . . . mission to . . . ensure an adequate supply of controls and also to detect diversion. So in order to do that effectively, you have to engage with the registrants."[57] I also agree with her recognition of "the importance of working with registrants—not just at workshops and conferences—but in writing that they can count on—to provide them all

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54 US-DEA-00021243 at 1248.

55 DEA_Rannazzisi-00000001 at 0011 ("Mar. 26, 2014 Rannazzisi Statement")

56 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 46:6-19 ("Q. . . . During your tenure in the Office of Diversion Control, did you believe it was important to communicate with distributors? A. Yes. Q. And does that include -- does that communication -- strike that. And does that include communicating with distributors to make sure that they understand what the DEA's expectations are? A. Yes. Q. Are you aware that the DEA has been criticized for its failure to communicate with the distributor community? A. Yes."); *id.* at 83:11-18 ("Q. . . . Why is it so important to work with registrants? A. It helps to ensure compliance. It's part of DEA's, Office of Diversion Control, mission to secure an -- ensure an adequate supply of controls and also to detect diversion. So in order to do that effectively, you have to engage with the registrants."); *id.* at 251:9-16 ("Q. And would you agree with me that communications between the Office of Diversion Control and distributors could help the distributors be more effective in minimizing diversion? A. It would help them better understand our regulations, which would, in turn, help minimize diversion.");

See Apr. 17, 2019 Dep. of Thomas Prevoznik at 363:22-364:3 ("Q. With respect to suspicious order monitoring, does DEA agree that providing registrants with clear guidance is important? A. I think clear guidance is very important.").

57 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 83:11-18.

the information and, especially, the certainty that they need to be in full compliance, as they want to be and as we expect them to be."[58]

However, the guidance provided by DEA was inadequate. For a long period of time, DEA refused to offer substantive responses to requests for additional guidance by registrants—registrants were left on their own to determine how to build a compliant system using DEA's open-ended requirements and vague suggestions. Although DEA would react to suspicious order monitoring programs that it deemed inadequate by taking action against registrants, it would not proactively assist registrants in designing or operating an effective system. Kyle Wright—a 22 year DEA veteran—testified in his February 28, 2019 deposition that he couldn't recall DEA providing any guidance whatsoever to manufacturer registrants regarding their suspicious order monitoring obligations.[59] And Thomas Prevoznik, testifying on behalf of DEA itself, acknowledged that aside from two letters sent by Rannazzisi to registrants in 2006 and 2007 (only one of which was sent to manufacturers) there was no additional industry-wide guidance to manufacturers regarding how to design or implement a compliant suspicious order monitoring system.[60]

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[58] *See id*., Exhibit 10 (Statement Before the Judiciary Committee United States Senate, "Oversight of the Ensuring Patient Access and Drug Enforcement Act" (Dec. 12, 2017)).

[59] *See* Feb. 28, 2019 Dep. of Kyle Wright at 192:1-6 ("Q: During the time period that you were involved in the distributor initiatives, are you aware of any guidance the DEA provided to manufacturer registrant regarding Suspicious Order Monitoring? A: Specifically, no."); *id.* at 193:5-10 ("Q: As you sit here today, can you remember any guidance whatsoever that the DEA provided to manufacturer registrants regarding their obligations under the Suspicious Order Monitoring regulation? A: No.").

[60] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 305:17-22 ("Q: Since 2007 and the letter from Joe Rannazzisi, has the DEA provided manufacturers with any further written guidance regarding the obligation to monitor suspicious orders? A: No."); *id.* at 285:16-21 ("Q: And aside from those 2006 and 2007 letters from Joe Rannazzisi, was there any other written guidance provided to manufacturers regarding how to identify a suspicious order? A: No."); *id.* at 178:19-179:9 ("Q: So essentially there was no industrywide guidance that was provided in 2008 or forward as to how to design or implement suspicious order monitoring systems, true? … A: Nationwide, correct. Q: Instead, one-off guidance was perhaps provided in the context of individual distributor meetings, correct? A: Yes. Along with the MOAs and the settlements that were done.").

Demetra Ashley—a senior executive at DEA's Office of Diversion Control— also remembers registrants regularly seeking clarification of their suspicious order monitoring requirements.[61] For example, on February 6, 2018, the National Association of Chain Drug Stores—a trade group that represents drug stores, supermarkets and mass merchants with pharmacies—sent a letter to Ashley requesting regulatory guidance and asking specific questions related to registrants' suspicious order monitoring obligations following *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*.[62]

Complaints from DEA registrants seeking additional clarification of the suspicious order monitoring requirements were common and were sometimes shared with me. But I also experienced a disconnect between what was going on in the field and what was shared with me as a Special Agent in Charge. Indeed, sometimes questions received from registrants—and DEA's subsequent response—were not directly sent to me. Instead, some of these communications were only distributed to Diversion Control personnel, who did not always share them with Special Agents in Charge.[63] Since Special Agents in Charge oversee Diversion Program Managers, DEA's failure to always inform Special Agents in Charge of such communications made it difficult to ensure that consistent guidance was being given by all DEA representatives, and in my opinion likely contributed to the confusion in the industry.

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[61] *See* Mar. 15, 2019 Dep. of Demetra Ashley at 58:23-59:3 ("Q. At any time during your tenure at the DEA, did you learn that the distributors were confused about their suspicious order regulations and wanted more guidance from the DEA? A. I can say in speaking with distributors, they expressed that they wanted more clarification."); *id.* at 240:14-20 ("Q. Is it also fair -- my understanding of your testimony, is it a fair summary that throughout your tenure at DEA, you understood that distributors were asking DEA for guidance because the implementing regulations was not crystal clear to them? A. Correct. They did express that."); *id.* at 186:1-25 (discussing how many times per month registrants would request guidance on how to comply: "I would say more than three, less than 10. That would be my estimate.").

[62] *See* MCKMDL00561146.

[63] *See, e.g.*, US-DEA-00005928; US-DEA-00005952; US-DEA-00005921; US-DEA-00005914.

I recall registrants regularly complaining that their requests for additional guidance or feedback were not being answered by DEA, or were being answered inconsistently.[64] For example, registrants asked for guidance on whether it was appropriate to raise a customer's controlled substance ordering limits;[65] whether certain types of know-your-customer documentation was required;[66] and whether they needed to modify their suspicious order monitoring or business practices in any way to achieve full compliance in the eyes of the DEA.[67] The Healthcare Distribution Management Alliance (now known as the "Healthcare Distribution Alliance") submitted twelve pages of detailed questions for DEA regarding suspicious order monitoring requirements in 2011, and another six pages of question in 2013.[68] Both sets of questions went unanswered for years.[69] Registrants also requested meetings with DEA and were often turned down.[70]

The Energy and Commerce Committee's investigation details distributors' concerns on the lack of guidance provided by DEA: "While the DEA has pointed to its Distributor Initiative program and other outreach efforts as a means of improving communications with distributors in recent years, distributors have voiced concern that the communication has been inadequate to

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64 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 219:7-17 (stating that she had discussions with others at DEA about how "registrants felt they were getting conflicting guidance."); US-DEA-00009355 at -9356 (reflecting conference feedback that "[A]lthough the speaker holds a top position with the DEA and diversion control, the answers and info provided was inconsistent with DEA…. The DEA continues to disseminate inconsistent information in open forums and in closed meetings. Distributors are not provided with clear consistent information.").

65 *See, e.g.*, US-DEA-00005928 at -5931.

66 *See, e.g.*, US-DEA-00005952 at -5954.

67 *See, e.g.*, US-DEA-00005921 at -5924.

68 *See* US-DEA-00008565 (2011 questions); US-DEA-00008577 (2013 questions).

69 *See* US-DEA-00008563 ("While the receipt of these questions was acknowledged by DEA staff (Cathy Gallagher), we never received a response to any of the questions or scenarios addressed in the correspondence. The attached 2013 questions were supposed to serve as a sort of agenda for a meeting with the Office of Diversion Control, but that meeting was canceled with relatively little notice.").

70 *See, e.g.*, US-DEA-00005914 at -5917 ("We did request that DEA hold a meeting with wholesalers, consumer groups, and community pharmacies so that all parties can clearly understand the expectations of DEA and can make every reasonable effort to comply. However, that request was flatly refused by DEA."); *see also* Mar. 15, 2019 Dep. of Demetra Ashley at 23:25-24:8 (discussing "meeting requests from industry"); *id.* at 50:2-16 (discussing "complaints we got" about DEA not accepting meetings with distributors).

provide meaningful guidance."[71] According to the Committee, DEA "informed registrants that it would not endorse a specific system for reporting suspicious orders and that distributors should no longer rely on explicit or implicit approval they may have received from the DEA in the past."[72] In his March 4, 2019 deposition, Kyle Wright also recalls "repeatedly" telling registrants that DEA will not approve or endorse a specific system for reporting suspicious orders.[73] After its investigation, the Committee recognized the need for additional guidance related to suspicious orders and made the following recommendation: "Congress should consider enacting additional suspicious order requirements to clarify registrant responsibilities and to supplement the suspicious order requirements recently codified in the SUPPORT Act."[74]

The GAO similarly recommended that DEA improve its guidance to registrants relating to their suspicious order monitoring and anti-diversion obligations. In 2015, GAO examined registrants' interactions with DEA concerning their CSA obligations.[75] The GAO found that "some distributors, individual pharmacies, and chain pharmacy corporate offices want improved guidance from, and additional communication with, DEA about their CSA roles and responsibilities. For example, 36 of 55 distributors commented that more communication or information from, or interactions with, DEA would be helpful."[76] Following its investigation, GAO recommended "that DEA take three actions to improve communication with and guidance

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71 *See* Dec. 19, 2018 Energy & Commerce Committee Report at 64.

72 *Id.* at 233; *see also* US-DEA-00001767 at 1771 (Dec. 27, 2007 letter to registrants: "DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.").

73 *See* Mar. 4, 2019 Dep. of Kyle Wright at 345:19-25 ("Q: In your experience, do you recall actually talking to registrants and telling them that the DEA does not approve or otherwise endorse a specific system for reporting suspicious orders? … A: Repeatedly.").

74 *See* Dec. 19, 2018 Energy & Commerce Committee Report at 323.

75 *See Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve their Understanding and Help Insure Access,* United States Government Accountability Office (June 2015), *available at* https://www.gao.gov/products/GAO-15-471.

76 *Id.*

for registrants about their CSA roles and responsibilities."[77] Specifically, "[i]n order to strengthen DEA's communication with and guidance for registrants" and support "the Office of Diversion Control's mission of preventing diversion while ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical needs," the GAO recommended that the Office of Diversion Control:

(1) "identify and implement means of cost-effective, regular communication with distributor, pharmacy, and practitioner registrants, such as through listservs or web-based training."

(2) "solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting."

(3) " solicit input from pharmacists, or associations representing pharmacies and pharmacists, about updates and additions needed to existing guidance for pharmacists, and revise or issue guidance accordingly."[78]

Given the lack of guidance from DEA to registrants, it is not surprising that former DEA agents were commonly hired by pharmaceutical companies who sought their expertise.[79] According to testimony from DEA officials in this case and my own experience, the vast majority of these companies wanted to comply.[80] Bringing in former DEA agents allowed these companies to gain insight into DEA's opaque requirements and remain compliant.

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77 *Id.*

78 *See id.*

79 *See* Eyre, Eric, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette-Mail (Feb. 18, 2017), *available at* https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd html.

80 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 329:14-22 ("Q. In your, frankly, remarkable career of rising from a secretary all the way up to an executive at DEA, isn't it the case, Ms. Ashley, that the vast majority of registrants with whom you dealt were trying to comply with the CSA and the implementing regs? . . . A: I agree with that, yes.").

Based on my recollection, DEA's justification for its refusal to provide additional suspicious order monitoring guidance was that the requirements were intentionally broad because there is no one size fits all suspicious order monitoring program—each registrant must design a system taking into account the unique needs of their own business. Kyle Wright remembers a similar justification for not providing guidance about suspicious order monitoring regulations: "Because it is fluid, and there are too many variables, too many anomalies, too many situations."[81] But such justifications do not explain why DEA refused to provide individualized feedback to registrants seeking guidance or feedback related to their own suspicious order monitoring programs or how they should handle specific suspicious ordering monitoring-related situations.

Of course, individualized feedback would require resources. But these resources could have been reallocated from other DEA programs. As I explain in Section III, DEA did not effectively allocate its resources and did not effectively work with registrants to identify solutions. Indeed, Thomas Prevoznik, testifying on behalf of DEA, repeatedly cited "investigations and litigation" to explain various gaps in DEA guidance and communication to registrants.[82]

C. Whitelaw's and Rafalski's claims that a compliant suspicious order monitoring system requires specific components has no basis in the applicable regulation and is inconsistent with DEA practice.

I reviewed Dr. Seth B. Whitelaw and James E. Rafalski's expert reports. Whitelaw provides extensive lists of the attributes he would expect to see in registrants' anti-diversion programs.[83]

[81] *See* Feb. 28, 2019 Dep. of Kyle Wright at 106:12-14.

[82] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 67:16-68:3 ("Q: And what is your understanding as to why there was a gap at least between 2010 to 2013 as to distributor conferences? A: In my research, it's because we were doing investigations and in litigation against quite a few registrants, particular distributors that communication was a little hard, in -- either in being -- either doing the investigation or in the midst of litigation."); *id.* at 200:24-201:15 (confirming that distributor initiative and conferences stopped in 2010 to 2013 "because of litigation and investigations"); *id.* at 223:12-19 (same); *id.* at 243:24-244:15 ("Q: If HDMA and the distributors sent a letter in 2011 asking the DEA a number of questions to which they hoped for clarification, I take it your response would be the reason the DEA didn't provide a response was because of litigation? … A: I don't think it was just litigation. I think it was ongoing investigations at that point.").

[83] *See* Apr. 15, 2019 Expert Report of Dr. Seth B. Whitelaw at 34-37.

Similarly, Rafalski provides a list of components that a suspicious order monitoring system and due diligence program "should include," and components that "one would expect to see" in an effective anti-diversion program.[84] While I don't endorse the accuracy of these lists, I note that such detailed program components were never set forth as affirmative requirements for compliance out of the mouth of the DEA or in any statute or regulation. Instead, DEA left registrants to fill in the details using the vague requirements in the regulations and a couple of guidance letters from DEA.

Whitelaw himself listed the guidance that he was able to derive from DEA communications to registrants:

> "By reviewing the DEA regulations and general guidance letters provided to all registrants during the review period, it is possible to get a clear concept of what a successful SOM program should look like. Below is a summarized list of SOM requirements derived from those sources:
>
> 1. The customer must be "known" to determine that the customer can lawfully receive the shipment.
> 2. There must be a designed system.
> 3. It must be operational.
> 4. It must identify suspicious orders of controlled substances.
> 5. Orders can be suspicious because of:
>   a. unusual size;
>   b. substantial deviation from a normal pattern; or
>   c. unusual frequency.
> 6. Once a suspicious order is discovered,
>   a. the local DEA Field Office must be informed, and
>   b. the order must be prevented from being filled until it can be ascertained that the order will not be diverted."[85]

Far from providing "a clear concept of what a successful SOM program should look like," this list leaves registrants with great discretion in designing their suspicious order monitoring systems. DEA expressly acknowledges that there is "more than one way to design and operate a

[84] *See* Apr. 15, 2019 Expert Report of James E. Rafalski at 36-40.
[85] *See* Apr. 15, 2019 Expert Report of Dr. Seth B. Whitelaw at 33.

system that can identify and report suspicious orders," that "there's no single feature that makes a suspicious order monitoring system compliant," and that it is "up to the registrant to design a system that works with its own business model and customer base."[86] Whitelaw and Rafalski's laundry list of attributes that compliant anti-diversion programs must contain is not mandated by DEA's broad and open-ended directives.

Indeed, given that DEA took the position that, when it comes to suspicious order monitoring, one size does not fit all, Whitelaw and Rafalski's claims that an acceptable suspicious order monitoring system must have specific aspects has no basis in the CSA, the federal regulations, or DEA's historical practice.

For example, Whitelaw claims that there was an obligation for manufacturers to "know their customers' customer."[87] I've never heard of such a thing, and neither did Kyle Wright.[88] Other DEA executives acknowledge that they were not always aware of any expectation to "know your customer's customer,"[89] nor could they point to any statute, regulation, formal notice, or correspondence communicating such a requirement.[90] And it's no wonder: DEA itself admits that

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86 *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 179:22-180:11.

87 *See* Apr. 15, 2019 Expert Report of Dr. Seth B. Whitelaw at 232.

88 *See* Feb. 28, 2019 Dep. of Kyle Wright at 201:24-202:1 ("Q. . . . Are you familiar with the phrase "know your customer's customer"? A. No.").

89 *See* Apr. 26, 2019 Dep. of Joseph Rannazzisi at 110:7-18 ("Q: Are you familiar with the phrase 'know your customer's customer?' A: I've heard that phrase. But that phrase was used after I -- I left. Q: Okay. So during your time as head of the Office of Diversion Control, 'know your customer's customer' was not a term that you were familiar with? A: No. Due diligence was the term we utilized. Due diligence on your customers. Making sure you know your customers and know what they're doing.").

90 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 159:20-161:8 ("Q: Going back to know your customer's customer, to your knowledge, is there any language in the Controlled Substance Act that states a manufacturer is required to know its customer's customer? A: In the Controlled Substances Act, No. Q: Is that phrase anywhere in the CSA to your knowledge? A: To my knowledge, no. Q: To your knowledge, is there any language in the Code of Federal Regulations that statues that a manufacturer is required to know its customer's customer? … A: I have to say I'm not sure on that one. … Q: As you sit here today are you aware of any statute that requires a manufacturer to know its customer's customer? A. No, I am not aware of a statute that says that. Q: What about a regulation? A. No, I'm not aware of a regulation that says that. Q: What about a formal notice that's been promulgated by DEA? . . . A: I'd have to say I don't know. Q: Are you aware of any correspondence from DEA to manufacturers explaining that manufacturers are responsible for knowing their customer's customer? A: I can't recall any.").

it did not communicate this so-called requirement to registrants in any sort of written industry-wide guidance.[91] Asked directly whether DEA "ever provided any kind of guidance to manufacturers informing them that they were to know their customers' customer," DEA representative Thomas Prevoznik flatly answered, "No, not to my knowledge."[92]

As another example, Whitelaw claims that manufacturers should have used chargeback data within their suspicious order monitoring systems to monitor downstream sales.[93] To my knowledge, there is no such requirement. Kyle Wright and Demetra Ashley also had no knowledge of an obligation to monitor chargeback data.[94] Even Thomas Prevoznik, speaking on behalf of DEA, testified that he had no knowledge of "any industrywide guidance indicating that manufacturers should review chargeback data."[95]

D. <u>If a company received no notification, action, or warning from DEA related to its suspicious order monitoring system even after regular audits, the</u>

[91] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 322:20-323:18 (stating that he had not heard the term "know your customer's customer" before 2011); *id.* at 325:8-12 ("Q: Has the DEA ever provided guidance to the industry in writing informing registrants that they are to know their customers' customers? A: Not that I'm aware of."); *id.* at 326:1-5 ("Q: [H]as the DEA ever provided any kind of guidance to manufacturers informing them that they were to know their customers' customer? A: No, not to my knowledge.").

[92] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 326:1-5.

[93] *See* Apr. 15, 2019 Expert Report of Dr. Seth B. Whitelaw at 36.

[94] *See* Feb. 28, 2019 Dep. of Kyle Wright at 220:20-221:3 ("Q: And I wanted to ask, in your understanding, what role, if any, do chargebacks play in Suspicious Order Monitoring? A: None. Q: Okay. A: None.").

See Mar. 15, 2019 Dep. of Demetra Ashley at 172:20-173:12 ("Q: Are you aware, as you sit here today, of an instance in which DEA informed all registrants that they should monitor chargeback data? … A: I am not. Q: Are you aware of any instance in which DEA informed manufacturers that there was a legal obligation to monitor chargeback data? A: I wouldn't want to say DEA. I'm aware that I have not. Q: Understanding your caveat there, are you aware of anyone else at DEA ever communicating to manufacturers that there was a legal obligation to monitor chargeback data? … A: I am not.").

[95] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 346:24-347:5 ("Q: At any point before [the Mallinckrodt distributor briefing on August 23, 2011], had the DEA ever issued any industrywide guidance indicating that manufacturers should review chargeback data? …A: Not to my knowledge.").

See also Apr. 26, 2019 Dep. of Joseph Rannazzisi at 120:6-21 ("Q: So DEA never issued any guidance to manufacturers informing them that charge-backs were to play a role in suspicious order monitoring, correct? … A: Besides the regulations and the C.F.R. -- in the CSA, no, I don't know if they ever issued a regulation -- any kind of document regarding chargebacks.");

registrant could expect that DEA did not find any violations of the relevant suspicious order monitoring laws and regulations.

DEA typically audits registrants every three to five years, depending on available resources, office workload, and work plan. During these audits, DEA inspects a registrant's compliance with various regulatory requirements, including suspicious order monitoring and the maintenance of effective controls against diversion. Because of the limited guidance or feedback from DEA about what a suspicious order monitoring system must contain (discussed in Sections II(A)-(C)), DEA did not have a specific checklist of system components that must be in place, other than the broad requirements of the federal regulation that the registrant have some system in place to detect and report suspicious orders. To verify these requirements were being met, DEA collected suspicious order monitoring policies and procedures, reviewed documents reflecting how these policies were applied in practice, and interviewed employees.

Based on my experience, it was reasonable for a registrant to expect that if DEA had a problem with the registrant's suspicious order monitoring policies and procedures, or if DEA believed that the registrant was not actually operating a system to effectively guard against diversion in practice, DEA would take some sort of action—at the very least, by informing the registrant of their deficiencies during a regular audit.[96]

[96] *See* Apr. 17, 2019 Dep. of Thomas Prevoznik at 130:2-12 ("A: So that's part of our review, when we go out and do scheduled investigations, is to review, are they in fact -- are they operating a system that can detect a suspicious order. Q: And that's something that the DEA reviews periodically as part of its auditing process, correct? A: Correct."); *id*. at 131:15-23 ("Q: And if either in the pre-registration process or in the audit process the DEA determines that a registrant's system is not adequately detecting suspicious orders, is that something that is conveyed to the registrant? A: Yeah, we -- we would tell them, you need to add something."); *id*. at 386:14-387:19 ("Q: If a registrant were failing to report suspicious orders in such a way that DEA believed it posed a threat to the public health, would it seek to suspend or revoke that registrant's registration? … A: There is a wide variety of things that we -- that we could do. We could take administrative actions. We could take civil actions. We could move to do an order to show cause. If we could show that there was imminent danger to the public -- public, we could go for immediate suspension order. We can do an injunctive action with the civil, or we can take criminal action. So there's a wide variety of different ways that we could go about it. Q: So it's fair to say that if the DEA believed a registrant posed a risk to public health because it was failing to report suspicious orders, it would take some sort of action, correct? A: Yes, correct.").

In cases of non-compliance, the registrant may receive a letter of admonition, in which case the registrant would have 30 days to respond and prove that corrective action was taken to remedy the problem identified. For more severe violations, DEA might take longer to inform the registrant of its findings. For example, DEA might develop a Memorandum of Understanding or Memorandum of Agreement with the registrant, which specifically identified corrective measures the registrant was required to take. But regardless of the specific approach, if DEA identified a regulatory violation, the registrant should learn about it during or after an audit. If a registrant received no specific feedback or follow-up after an audit, the registrant could expect that DEA did not identify any violations of the relevant laws or regulations.[97]

III. DEA COULD HAVE MORE EFFECTIVELY ALLOCATED ITS RESOURCES TO CURB THE GROWTH OF THE OPIOID ABUSE CRISIS.

As Special Agent in Charge, I was responsible for managing the budget for the Washington Division Office, which encompasses Maryland, West Virginia, Virginia, and the District of Columbia. In this role, I was tasked with requesting resources and developing proposals on how to allocate them to best fight the opioid abuse crisis. My opinions below draw from my experience (described in greater detail in Section I(A) and Exhibit A).

A. DEA failed to allocate sufficient resources to the geographic areas in greatest need.

Despite my best efforts, I was never able to obtain sufficient resources to provide the level of DEA operations my region required. The states under my purview required more resources than most other jurisdictions. My biggest area of concern was West Virginia, a state at the epicenter of

[97] I am not aware of any DEA actions—including civil or administrative actions, letters of admonition, notices of violation, orders to show cause, etc.—against Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Cephalon, Inc., or Teva Pharmaceuticals USA, Inc., nor any of their current or prior affiliates or subsidiaries, at any time related to their suspicious order monitoring obligations.

the opioid abuse crisis. A December 19, 2018 report authored by the Energy and Commerce Committee details the extent of West Virginia's opioid-related issues:

> "The opioid epidemic's impact has been particularly acute in West Virginia . . . Between 1999 and 2004, the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent, giving West Virginia the highest unintentional drug overdose death rate in the United States at the time . . . In 2017, West Virginia continued to have the highest overdose death rate in the country, and a report issued by the West Virginia Department of Health and Human Resources found that the number of overdose deaths in the state increased by more than 316 percent between 2001 and 2016, with most overdose deaths involving at least one opioid."[98]

DEA knew of the unique challenges facing West Virginia for years. DEA was "put on notice by the Department of Justice's (DOJ) Office of Inspector General (OIG) in 2002 that it had not dedicated the requisite level of resources to address the growing problem of controlled substance diversion in West Virginia."[99] By 2007, a DEA fact sheet indicated that "diversion was a significant problem in West Virginia, which led the nation in methadone-related deaths per capita and had the fastest-growing rate of methadone overdoses."[100] And, in 2011, DEA was aware that diversion issues in West Virginia were still "on the rise" and that drug trafficking organizations selling the diverted medications were "particularly active" in the state.[101]

Despite its awareness of West Virginia's plight, DEA failed to allocate sufficient resources to West Virginia. In 2006, while West Virginia (along with New Mexico) suffered from the highest overdose death rate in the country, there were still only two Diversion Investigators assigned to West Virginia.[102] This shortage of Diversion Investigators is especially puzzling given that the relatively few number of Diversion Investigators was central to the OIG's 2002 finding of

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98 Dec. 19, 2018 Energy & Commerce Committee Report at 25.
99 *Id.* at 46.
100 *Id.* at 49.
101 *See id.* at 51.
102 *See id.* at 10.

inadequate DEA resources.[103] Before 2013, West Virginia also suffered from a complete lack of DEA leadership—the state's highest-ranking DEA agent during this period was a group supervisor, who was expected to run enforcement operations.[104]

As Special Agent in Charge, I fought hard to bring increased resources into West Virginia. I recall making frequent requests to DEA for additional resources in West Virginia, including requests for Tactical Diversion Squads and an Assistant Special Agent in Charge based in West Virginia. An injection of such DEA resources would have been welcome news to communities and the local police departments serving them. Indeed, many local police departments have very few resources of their own and are unable to muster an adequate response to the opioid abuse crisis independently.[105] However, my requests for additional resources were frequently denied.

When I appealed up the chain for more resources in West Virginia, I was told to take the resources from other states in my division. This was not a feasible solution. The other states under my purview also suffered from extensive drug-related issues and required considerable resources. In 2016, the District of Columbia experienced the highest age-adjusted heroin-related death rate in the United States, followed closely by West Virginia.[106] Opioid-related deaths in Maryland nearly tripled from 2006 to 2017.[107] And, in Virginia, deaths from prescription opioid abuse

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[103] *See id.* at 47-48; *see also* Memo to Asa Hutchinson, Administrator, DEA from Glenn A. Fine, Inspector General re *Review of the Drug Enforcement Administration's Investigations of the Diversion of Controlled Pharmaceuticals, Report Number I-2002-010* (2002), *available at* https://oig.justice.gov/reports/DEA/e0210/final.pdf.

[104] *See* Eyre, Eric, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette-Mail (Feb. 18, 2017).

[105] *See The opioid epidemic is changing law enforcement*, Newsday (Sept. 28, 2017), *available at* https://www.newsday.com/opinion/commentary/the-opioid-epidemic-is-changing-law-enforcement-1.14293926; *What happens when you're the only cop in town?*, USA Today, *available at* https://www.usatoday.com/story/opinion/policing/spotlight/2018/10/24/law-enforcement-cops-policing-usa-marshall-project/1616217002/.

[106] *See* 2018 National Drug Threat Assessment, DEA, *available at* https://www.dea.gov/documents/2018/10/02/2018-national-drug-threat-assessment-ndta ("2018 Nat'l Drug Threat Assessment") at 15.

[107] *See* Prudente, Tim, *Two Maryland doctors indicted on drug charges after allegedly writing prescriptions for more than a quarter-million doses*, Baltimore Sun (Aug. 10, 2017), *available at* http://www.baltimoresun.com/news/maryland/crime/bs-md-doctors-indicted-20170810-story.html.

increased by 1,578 percent from 1999 to 2013.[108] Moreover, the states within my region also needed resources to fight drugs other than opioids; the District of Columbia, for example, had a major issue with synthetic cannabinoids, which required extensive resources (*e.g.*, laboratory analyses of chemical composition).[109] Re-allocating more of my division's resources to West Virginia would have just shifted West Virginia's resource problem elsewhere.

In my role overseeing all DEA operations in West Virginia, Virginia, Maryland, and the District of Columbia, my responsibilities often extended into bordering states with common, interrelated issues. Most notably, I recall my team in West Virginia regularly working with our counterparts in Ohio to reduce the flow of drugs within and between these neighboring states—drug dealers don't stop at the Ohio-West Virginia border, and neither did my team in West Virginia. Effective enforcement of drug laws in one of these states, benefits the other. Indeed, if DEA takes down an interstate drug dealer based in Southern Ohio, we help reduce the amount of illicit drugs entering West Virginia. For example, I recall a West Virginia-based task force (specifically, the Brooke-Hancock-Weirton Drug and Violent Crimes Task Force) assisting in an 18-month investigation headed by an Ohio task force, which resulted in the arrest of 27 Ohio residents and five West Virginia residents for drug-related offenses, primarily relating to heroin.[110]

This connection between West Virginia and Ohio is part of a larger connection between several Midwest states. Specifically, I recall using West Virginia resources to assist in investigations designed to stem the flow of illicit drugs from Detroit to West Virginia and other

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[108] *See* Worker, Andrea, *Learning to Face Opioid Overdose Crisis; Chris Atwood Foundation hosts training on opioid overdose reversal*, The Herndon Connection (Virginia) (Aug. 30, 2017), *available at* http://www.connectionnewspapers.com/news/2017/aug/30/learning-face-opioid-overdose-crisis/.

[109] *See* Anderson, Jeffrey, *Spice World* Vol. 35, No. 36 at 14 (Sept. 2015), *available at* https://www.washingtoncitypaper.com/news/article/13047146/spice-world-synthetic-drugs-have-plagued-dc-for-years-what.

[110] *See* Gosset, Dave, *32 suspected drug dealers face arrest in Steubenville*, Herald-Star, (Aug. 26, 2016), *available at* http://www.heraldstaronline.com/news/local-news/2016/08/32-suspected-drug-dealers-face-arrest-in-steubenville/.

Midwest states, which has been referred to as a drug "pipeline" responsible for the resurgence of heroin addiction in the region.[111] Due to their lack of rival gangs, Michigan drug dealers saw West Virginia, Ohio, Kentucky, Pennsylvania, and Tennessee as new markets ripe for exploitation.[112] We could not stand idly by while illicit drugs from Detroit poured into West Virginia; in the words of Mike Stuart (the United States Attorney for the Southern District of West Virginia), "[n]o longer will we tolerate the folks from Detroit coming to our town, violating our citizens, bringing misery and chaos. Those days are over."[113] To reduce the amount of illicit drugs flowing through this pipeline, West Virginia federal, state, and local law enforcement teamed up with their counterparts from other states to take down a drug ring operating in West Virginia, Michigan, and Ohio, which resulted in the seizure of "enough fentanyl to kill a quarter million people."[114] Due to this connection between West Virginia and its surrounding region, the resource issues I faced in West Virginia also had negative impacts on nearby states.

My persistent requests for additional resources didn't gain traction until late in my tenure. In 2016, leadership issues were addressed by assigning an Assistant Special Agent in Charge, who is based in Charleston, West Virginia, rather than Washington D.C.[115] While sitting on an expert panel at a West Virginia public forum in late 2017, I noted how my pleas for help in West Virginia were finally being heard: "[T]his problem has outgrown everybody . . . I had to sell that to my

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111 *See* Stafford, Kat *Feds: Michigan Drug 'pipeline' tied to heroin resurgence*, Detroit Free Press (Aug. 26, 2015), *available at* https://www.freep.com/story/news/local/michigan/2015/08/26/feds-michigan-drug-pipeline-heroin-resurgence/32412437/.

112 *See* Stafford, Kat *Feds: Michigan Drug 'pipeline' tied to heroin resurgence*, Detroit Free Press (Aug. 26, 2015).

113 *See Dozens arrested in major drug bust in West Virginia*, Los Angeles Times via the Associated Press (Apr. 17, 2018), *available at* https://www.latimes.com/nation/la-na-west-virginia-drug-bust-20180417-story html.

114 *See* Siemaszko, Corky, *Fentanyl seized, 90 arrested in takedown of 3-state drug ring*, NBC News, (Apr. 17, 2018), *available at* https://www.nbcnews.com/storyline/americas-heroin-epidemic/fentanyl-seized-90-arrested-takedown-3-state-drug-ring-n866841.

115 *See* Dec. 19, 2018 Energy & Commerce Committee Report at 9.

people in DEA headquarters who didn't believe. Now, they do."[116] DEA also put more boots on the ground, hiring additional agents and setting up Tactical Diversion Squads.[117] Notably, by 2018, there were six Diversion Investigators assigned to West Virginia.[118]

I believe this influx of resources led to considerable improvement in West Virginia and surrounding states with interrelated issues, such as Ohio. But significant—and avoidable—damage had already been inflicted. I agree with the Energy and Commerce Committee's finding that if "the DEA assigned more personnel to West Virginia sooner or more effectively utilized the tools it possessed to identify, and combat diversion, perhaps the human and economic toll of the opioid epidemic in West Virginia may have been less severe."[119] The ideal solution would have been to allocate more resources to fight the opioid abuse crisis across the country. But, at the very least, states with the greatest needs, such as West Virginia, should have received additional resources. Instead, DEA adopted an "if we do it for one, we need to do it for all" mentality. In my opinion, this failure to prioritize regions with the greatest need contributed to the growth of the opioid abuse crisis. As I explain in the next section, in addition to being scarce, the resources in my division were not properly balanced across different programs.

B. DEA could have struck a better balance when allocating its resources across different programs.

Based on my 32 years of experience in DEA, fighting drug abuse requires a balance of law enforcement, diversion control, and community engagement. We cannot arrest away the opioid

[116] *See* Conley, Ben, *Panel discusses opioid epidemic at public forum*, The Dominion Post (Morgantown, West Virginia) (Dec. 5, 2017).
[117] *See* Eyre, Eric, *DEA agent: 'We had no leadership' in WV amid flood of pain pills*, Charleston Gazette-Mail (Feb. 18, 2017); Dec. 19, 2018 Energy & Commerce Committee Report at 9.
[118] *See id*. at 51-52.
[119] *See id.* at 98-99.

abuse crisis. To come up with solutions, we need to engage with both registrants and the community at large, listen to their concerns, and work together to address them.

DEA's 360 Strategy—which was rolled out towards the end of my tenure—is a good example of this balanced approach. The goals of DEA 360 are listed below:

- (1) "Stopping the deadly cycle of heroin and opioid pill abuse by eliminating drug trafficking organizations and gangs fueling violence on the streets and cycles of addiction in our communities"
- (2) "Partnering with the medical community and others to raise awareness of the dangers of prescription opioid misuse and the link to heroin"
- (3) "Strengthening community organizations best positioned to provide long-term help and support for building drug-free communities"[120]

DEA seeks to accomplish these goals through a three-pronged strategy:

- (1) **Law Enforcement**: "Coordinated Law Enforcement operations targeting all levels of drug tracking organizations and violent gangs supplying drugs to our neighborhoods"
- (2) **Diversion**: "Engaging drug manufacturers, wholesalers, practitioners, and pharmacists through Diversion Control to increase awareness of the opioid epidemic and encourage responsible prescribing practices, and use of opioid painkillers throughout the medical community"
- (3) **Community Outreach**: "Community Outreach and partnership with local organizations following enforcement operations, equipping and empowering communities to fight the opioid epidemic"[121]

In my opinion, DEA 360 correctly recognizes the importance of a balanced approach to fighting the opioid abuse crisis. It acknowledges the importance of engaging with community members, including registrants, medical providers, local organizations, and individual constituents. But this balanced approach should and could have been adopted ten years before it was. Indeed, DEA did not roll out the 360 Strategy until 2016, when it was deployed in Pittsburgh,

[120] DEA Website, DEA 360 Strategy, *available at* https://www.dea.gov/360-strategy.
[121] *Id.*

Louisville, Milwaukee, and St. Louis.[122] Since that time, DEA has started deploying DEA 360 in other pilot cities, but it took until 2017 for it to place pilot cities in West Virginia (Charleston) and Ohio (Dayton).[123] When announcing the roll out of the 360 Strategy in West Virginia, I noted how its multifaceted approach was sorely needed:

> "The communities in West Virginia have been and continue to be among the hardest hit by the heroin and opioid epidemic. The DEA 360 Strategy is a framework for introducing a comprehensive and sustained multi-layered approach to attack this epidemic. By bringing together all the resources of our local, state, and federal partners, we look to loosen the hold this epidemic and illicit drug trafficking organizations have on the Tri-County area."[124]

Beyond the DEA 360 pilot cities, a more balanced approach to fighting the opioid abuse crisis was finally rolled out in other parts of my division near the end of my tenure. For example, in Virginia, DEA participated in the "Hampton Roads Heroin Working Group." Created in September 2016, this program took a holistic, community-driven approach to fighting the opioid abuse crisis. When commenting on the Hampton Roads Heroin Working Group in 2017, I praised its use of collaboration to identify solutions: "DEA is proud to be part of the Hampton Roads Heroin Working Group . . . We are keenly aware of the benefits of the collaborative efforts promoted by this group. These efforts are essential to our continued fight against the heroin and opioid abuse crisis that is plaguing the Hampton Roads community."[125]

Joe Rannazzisi paid lip service to the importance of registrant and community engagement, testifying in July 2012 that one of DEA's roles "is to educate the registrant population . . . on their

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[122] Although listed (along with Louisville, Milwaukee, and St. Louis) as a 2016 Pilot City, DEA 360 was rolled out in Pittsburgh in November 2015. *See id.*

[123] Among others, DEA also added Baltimore as a pilot city in 2018 and Cleveland as a pilot city in 2019. *See id*.

[124] *See* Press Release, *DEA Announces "360 Strategy" In Charleston To Huntington, West Virginia Tri-County Area*, DEA (Feb. 15, 2017), *available at* https://www.dea.gov/press-releases/2017/02/15/dea-announces-360-strategy-charleston-huntington-west-virginia-tri-county.

[125] *See* Press Release, *One Year Since Launch, Hampton Roads Opioid Working Group Maintains Commitment to Combating Opioid Epidemic*, Office of the Attorney General, Commonwealth of Virginia (Sept. 28, 2017), *available at* https://oag.state.va.us/media-center/news-releases/1045-september-28-2017-one-year-since-launch-hampton-roads-opioid-working-group-maintains-commitment-to-combating-opioid-epidemic.

obligations under the CSA, as well as to educate parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the problem, and how to best address prescription drug diversion in communities throughout the United States."[126] But, in reality, the Office of Diversion Control under Joe Rannazzisi was focused on prosecuting pharmaceutical companies,[127] and did not engage with registrants and the broader community.

Rannazzisi "brought an aggressive approach to the diversion control office."[128] His office "initiated a record number of administrative actions; the government collected record-setting civil penalties."[129] But Rannazzisi refused to work cooperatively with the industry to identify solutions, a key component to a successful enforcement program.[130] According to Matthew Murphy, a veteran DEA supervisor whom Rannazzisi hired to be chief of pharmaceutical investigations, Rannazissi "wasn't viewed as a person [the industry] could work with. And maybe that was appropriate. He didn't want to work with industry much."[131] Rannazzisi was unfazed by industry complaints about a lack of cooperation from DEA: "We're worried about their feelings being hurt because we were doing our job?" . . . "We were making them comply. We were holding their feet to the fire."[132] When a superior questioned his failure to communicate and cooperate with the

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[126] *See* US-DEA-00019479 at 9481.

[127] *See Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, 60 Minutes (June 17, 2018), *available at* https://www.cbsnews.com/news/60-minutes-ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.

[128] *See* Higham, Scott & Bernstein, Lenny, *The Drug Industry's Triumph Over The DEA*, The Washington Post (Oct. 15, 2017), *available at* https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?noredirect=on&utm_term=.cc814ae19607.

[129] *See id.*

[130] *See* Apr. 3, 2019 Dep. of Keith Martin at 85:10-19 ("Q: Would you agree that based on your experience as an agent, successful leaders at DEA are willing to be the first one to the table to share information with folks who might be able to reciprocate and help the DEA . . . A: I will say that there are many factors to that, being a great leader or a good leader. That's one of them, yes"); *id.* at 85:20-86:7 ("Q: . . . Is it fair to say that treating potential collaborators as adversaries is not an effective way to to build successful cases at DEA? . . . A: Again, you know, it depends on the situation and what information there is, but I - - we work with everyone. Q: And you work with everyone because if they can help you achieve your mission, that's good for you? A: A team is better than one.").

[131] *See* Higham, Scott & Bernstein, Lenny, *The Drug Industry's Triumph Over The DEA*, The Washington Post (Oct. 15, 2017).

[132] *See id.*

industry, Rannazzisi told his staff: "Now this is war . . . We're going after these people and we're not going to stop. We're just going to continue to move forward. And we don't really give a damn any more what the department wants."[133]

After leading a "decade-long campaign of aggressive enforcement," Rannazzisi was "forced out" in 2015 and replaced by Louis Milione.[134] Around the same time, the Justice Department named Chuck Rosenberg as the new DEA chief. Rosenberg sought to "mend the rift between the agency and the drug industry."[135] Senator Orrin Hatch applauded Rosenberg for improving "the DEA's relationship with supply chain stakeholders."[136] In response, Rosenberg acknowledged that the agency has been slow to address industry's concerns and had failed to communicate with them: "The overwhelming majority, 99 plus percent, are our allies in this thing . . ."[137] In her deposition, Demetra Ashley confirmed that DEA increased its engagement with registrants under Milione due to complaints by registrants that guidance was lacking.[138] Registrants eagerly absorbed the information provided by DEA's increased outreach efforts; for example, I recall large turnouts at Pharmacy Diversion Awareness Conferences, which provide free training to help pharmacy personnel identify and prevent diversion.[139]

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133 *See id.*
134 *See id.*
135 *See id.*
136 *See id.*
137 *See id.*
138 *See* Mar. 15, 2019 Dep. of Demetra Ashley at 21:16-22:1 (discussing changes to DEA's approach under Milione: ". . . So one of the things that Lou and I discussed when we -- we both reported at the same time is that we wanted to have, you know, more training, lots of engagement because we felt that -- well, actually not we felt that. We were told by industry that they weren't engaging with DEA enough. They needed clarification and policy. So we felt that we should do a lot more of that, so that was one of the initiatives we placed out to the field and asked them to, you know, just do more engagement."); *id.* at 50:2-10 (discussing changes to DEA's approach under Milione: ". . . So at the time I was there in headquarters working for Lou . . . the changes were that we were accepting meetings in the headquarters office from registrants. We have a directive out to the field to increase their engagement. We turned back on a few initiatives that . . . weren't given as much attention.").
139 *See* MEDIA ADVISORY: *DEA To Conduct Pharmacy Diversion Awareness Conference In Pittsburgh As Part Of The 360 Strategy To Address The Diversion Of Prescription Opioids*, DEA (Dec. 8, 2015), *available at* https://www.dea.gov/press-releases/2015/12/08/media-advisory-dea-conduct-pharmacy-diversion-awareness-conference.

In addition to its failure to engage with the registrant community, I believe DEA also failed to dedicate enough resources to communicating with the broader community, (such as local constituents and organizations that were impacted by the opioid abuse crisis) prior to introducing DEA 360. There is no way to understand a community's unique drug abuse issues or needs without pounding the pavement and speaking to its members. I did this myself as much as I could. For example, I participated in town halls and panels with community members that were impacted by the opioid abuse crisis. Such events were vital to accomplishing my duties, as they afforded me the opportunity to identify areas of need and uncover potential solutions. Engaging with doctors and other health care experts also provides insight to law enforcement on the importance of prevention and treatment—rather than simply enforcement—in the fight against opioid abuse.

For example, at an August 2015 summit held by federal officials related to a heroin resurgence in the Midwest, Steven Dettelbach—U.S. attorney for the Northern District of Ohio—stressed the importance of discussing addiction prevention strategies with doctors and noted that "[w]e are not going to enforce and arrest our way out of this incredibly difficult problem."[140] I agree that we cannot arrest our way out of the opioid abuse crisis. Unfortunately, as explained in the prior section, we did not have enough resources, and prior to DEA 360, the limited resources we had were not allocated in a balanced manner across enforcement, diversion control, and community engagement. As explained in the following section, DEA did not even use ARCOS and suspicious order reports—diversion control resources it was given by registrants—effectively.

IV. DEA HAD EXCLUSIVE ACCESS TO DATA THAT WAS CRUCIAL TO FIGHTING THE OPIOID ABUSE CRISIS, BUT DID NOT MAKE EFFECTIVE USE OF THIS DATA.

[140] *See Feds: Michigan drug 'pipeline' tied to heroin resurgence*, Detroit Free Press (Aug. 26, 2015), *available at* https://www.freep.com/story/news/local/michigan/2015/08/26/feds-michigan-drug-pipeline-heroin-resurgence/32412437/.

Like my opinions in Section II, I developed the below opinions based on my extensive experience in diversion-related matters over my 32 year tenure at DEA (described in Section I(A) and Exhibit A).

A. DEA did not effectively use its exclusive access to complete, aggregated ARCOS data to combat the opioid abuse crisis.

Under the CSA, pharmaceutical manufacturers and distributors are required to report their controlled substance transactions to DEA. To this end, they use ARCOS ("Automation of Reports and Consolidated Orders System"), a system which tracks the movement of controlled substances "from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level."[141] This transaction data is then reported to DEA, which can use it to detect the diversion of controlled substances.[142]

However, during much of the opioid abuse crisis, DEA did not effectively use ARCOS proactively to identify diversion trends; instead, ARCOS was used reactively, to strengthen cases against targets identified through other methods.[143] Indeed, when the Energy and Commerce Committee reviewed data previously submitted to DEA by pharmaceutical manufacturers and distributors, "it was able to identify large increases in hydrocodone and oxycodone shipments to West Virginia pharmacies that should have merited closer inspection by DEA at the time."[144] By not effectively using such data, DEA contributed to the worsening of the opioid abuse crisis in West Virginia. As Special Agent in Charge of the region encompassing West Virginia, I agree with the Energy and Commerce Committee's finding that, "[t]he DEA had long-standing knowledge that controlled substance diversion was an issue that plagued West Virginia. Had the

[141] *See* DEA Website: Diversion Control Division, *Automation of Reports and Consolidated Orders System (ARCOS), available at* https://www.deadiversion.usdoj.gov/arcos/index.html.
[142] *See id.*; Dec. 19, 2018 Energy & Commerce Committee Report at 9, 53.
[143] *See id*. at 9, 47.
[144] *See id.* at 53-54.

DEA better used ARCOS data to identify potentially problematic pharmacies, it could have better leveraged its resources to combat diversion in West Virginia."[145]

DEA's failure to use ARCOS data effectively was not limited to West Virginia. When testifying before members of the Energy and Commerce Committee, acting DEA director Robert W. Patterson said that during the height of the opioid abuse crisis, ARCOS was compiled manually, making it a reactive—rather than proactive—tool.[146] As Thomas Prevoznik acknowledged in his deposition, under Rannazzisi's leadership, DEA had no policies in place governing how ARCOS was to be used to generate leads, nor any structure to keep track of any investigations or formal actions resulting from any leads.[147]

DEA's failure to effectively use its ARCOS data is especially troubling since only DEA has access to the complete, aggregated ARCOS data from all manufacturers and distributors. Although manufacturers and distributors often asked to see aggregated ARCOS data to help make informed decisions on whether to supply a customer, DEA denied such requests.[148] As a result,

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[145] *See id.* at 57.

[146] *See* Zezima, Katie, *House Energy and Commerce Committee grills DEA chief over free flow of opioids*, Washington Post (Mar. 20, 2018), *available at* https://www.washingtonpost.com/national/house-energy-and-commerce-committee-grills-dea-chief-over-free-flow-of-opioids/2018/03/20/76a79e24-2c68-11e8-b0b0-f706877db618_story.html?noredirect=on&utm_term=.076ee28a8ee7.

[147] *See, e.g.*, Apr. 18, 2019 Dep. of Thomas Prevoznik at 511:5-512:10 ("Q: Okay. Between 2006 and 2015 under Mr. Rannazzisi's leadership, did DEA have any published policy about what happens after an ARCOS lead is generated? A. Not to my knowledge. Q. Between 2006 and 2015, under Mr. Rannazzisi's leadership, did DEA have any process where it maintained any report indicating how many ARCOS leads were sent to DEA field investigations for investigation? . . . A: Not to my knowledge. Q: Between 2006 and 2015, under Mr. Rannazzisi's leadership, did DEA have any process where it maintained any report indicating how many ARCOS leads were actually investigated at the field division level? A: Not to my knowledge."); *id.* at 512:11-514:4 (indicating that under Mr. Rannazzisi's leadership, DEA had no process where it maintained any report to indicate how many immediate suspension orders, orders to show cause, convictions, indictments, or other formal actions by DEA resulted from ARCOS leads).

[148] *See* Mar. 15, 2019 Dep. of Demetra Ashley at 135:21-136:18 ("Q. . . . the sentence reads manufacturers and distributor have consistently expressed a desire for assistance from DEA in fulfilling these obligations and have requested ARCOS information to help them make informed decisions about whether new customers are purchasing excessive quantities of controlled substances. Based on your experience working at the DEA; is that a true statement? A. Yes, that is. Q. And that is something which the distributors have been asking for since at least 2010, correct? . . . A: In my personal experience, they've asked for it.").

manufacturers and distributors could only see one piece of the puzzle—their own ARCOS data—whereas DEA had the ability to put the pieces together and see the whole picture.[149]

Only in recent years has DEA began to more effectively use ARCOS data as a tool to proactively generate leads. In 2017, for example, DEA headquarters began sending target packages to field divisions that included ARCOS analyses, an action that Prevoznik acknowledged was an improvement over prior practice.[150] In addition, DEA finally took steps to allow registrants more access to ARCOS data in February 2018, when it announced a feature allowing distributors and manufacturers "to view the number of businesses that had sold a particular controlled substance to a prospective customer during the prior six months."[151] Upon announcing this new feature, DEA noted how it would assist manufacturers and distributors by helping them "evaluate whether a new customer posed a risk for diversion."[152] DEA also launched a coalition with states, under which DEA provides states with access to ARCOS data, and states provide DEA with prescription drug monitoring program data.[153] Just recently, in February 2019, DEA announced that it would implement one of the Energy & Commerce Committee's recommendations reflected in H.R. 6 (the

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[149] *See* Feb. 28, 2019 Dep. of Kyle Wright at 170:2-14 ("Q. Just to make sure the record is clear, each distributor provided their own ARCOS data to the DEA, correct? A. Correct. Q. And the DEA did not take distributor -- one distributor's ARCOS data and share it with another distributor, correct? A. Not to my knowledge. Q. And did the same apply for pharmacies? A. It applied to all registrants. Q. And manufacturers as well? A. All registrants."); *id.* at 218:17-21 ("Q. Besides the DEA and other law enforcement entities, do any private parties have access to ARCOS data? . . . A: No."); Dec. 19, 2018 Energy & Commerce Committee Report at 60 ("The DEA currently makes only a summary of ARCOS data publicly available . . . Amid the opioid crisis, some have called for greater transparency of ARCOS data. For example, the Healthcare Distribution Alliance, an association representing major wholesale drug distributors, has said it would be helpful for distributors to have access to "aggregated and blinded purchasing data from the ARCOS database' in order to compare their own customers' orders against the total amount of controlled substances the customer receives from all distributors.").

[150] *See* Dec. 19, 2018 Energy & Commerce Committee Report at 9, 47; *see also* Apr. 18, 2019 Dep. of Thomas Prevoznik at 509:16-510:5 ("Q. Fair to say that DEA's current leadership has improved how DEA uses ARCOS data in its diversion investigations after Mr. Rannazzisi retired in 2015? . . . A: I'm not sure what you mean by improvements . Q. Well, like using threat assessments and sending those to the field. You view those as a good thing, right? A: Yes.").

[151] *See* Dec. 19, 2018 Energy & Commerce Committee Report at 59.

[152] *See id.*

[153] *See* Davis, Jessica, *DEA partners with states to share prescription data in opioid fight*, Healthcare IT News (Apr. 19, 2018), *available at* https://www healthcareitnews.com/news/dea-partners-states-share-prescription-data-opioid-fight.

SUPPORT for Patients and Communities Act) by establishing a data platform capable of providing more real time data to pharmaceutical manufacturers and distributors[154]—previously, the ARCOS data received was several months old. In March 2018, acting DEA director Robert W. Patterson discussed DEA's recent efforts to modernize ARCOS, while acknowledging DEA's failure to use this tool effectively in the past: "I can say repeatedly in '08, '09, '10, we did not use this data in the way that we are now using it . . . Where we fell short, we'll take responsibility for it."[155]

B. DEA did not effectively utilize suspicious order reports submitted by registrants.

DEA also did not effectively use suspicious order monitoring reports submitted to it by registrants. Registrants often complained about the lack of visibility concerning how DEA used the suspicious order reports provided to it.[156] Consistent with these complaints, the Energy and Commerce Committee found many examples where DEA received suspicious order monitoring reports, but did not take any visible course of action in response: "The Committee's investigation found many instances in which distributors sent suspicious order reports to the DEA or otherwise apprised the agency of concerning activity by doctors or pharmacies, but what action the DEA took in response, if any, was not clear."[157] In addition, Thomas Prevoznik testified that, to his knowledge, DEA didn't have any policies or procedures related to the review, analysis, or investigation of suspicious order reports under Rannazzisi's leadership.[158]

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[154] *See* Press Release *DEA Implementing Provision from SUPPORT Act to Help Registered Drug Manufacturers & Distributors Combat Opioid Crisis*, House Energy and Commerce Committee Republicans (Feb. 26, 2019), *available at* https://republicans-energycommerce house.gov/news/dea-implementing-provision-from-support-act-to-help-registered-drug-manufacturers-distributors-combat-opioid-crisis/.

[155] *See* Zezima, Katie, *House Energy and Commerce Committee grills DEA chief over free flow of opioids*, Washington Post (Mar. 20, 2018), *available at* https://www.washingtonpost.com/national/house-energy-and-commerce-committee-grills-dea-chief-over-free-flow-of-opioids/2018/03/20/76a79e24-2c68-11e8-b0b0-f706877db618_story.html?noredirect=on&utm_term=.076ee28a8ee7.

[156] *See* Dec. 19, 2018 Energy & Commerce Committee Report at 10.

[157] *See id.* at 60.

[158] *See* Apr. 18, 2019 Dep. of Thomas Prevoznik at 558:8-17 ("Q. Between 2006 and 2015 under Mr. Rannazzisi's leadership, did DEA have a published policy that ensured that someone at DEA would investigate every suspicious order report that DEA received? . . . A: Not that I'm aware of."); 564:16- 565:5 ("Q: Between 2006 and 2015, under

Although the bulk of my report so far has dealt with manufacturers and distributors of prescription opioids, as I explain in the next section, other parties (*e.g.*, pill mills, internet pharmacies, rogue doctors) and drugs (*e.g.*, heroin and fentanyl) were a bigger concern for DEA based on my experience. The prioritization of these concerns may explain why DEA failed to sufficiently utilize the ARCOS and suspicious order reports it was provided.

V. REDUCING THE IMPACT OF ILLEGAL OPIOIDS, SUCH AS STREET OPIOIDS AND PRESCRIPTION OPIOIDS OBTAINED THROUGH ILLICIT SOURCES, HAS BEEN THE DEA'S PRIMARY FOCUS DURING THE OPIOID ABUSE CRISIS.

For most of my time at DEA, illegal street drugs—such as heroin, crack cocaine, cocaine, and methamphetamine—were by far our greatest concern. But, in my later years at DEA, the attention DEA placed on diverted prescription opioids grew. In fighting diversion, we dealt more frequently with sources of diversion such as internet pharmacies (*e.g.*, Operation Cyber Chase),[159] pill mills, and doctor shopping, than with pharmaceutical manufacturers or distributors. My extensive experience in these areas (described in greater detail in Section I(A) and Exhibit A) informed my opinions below.

the leadership of Mr. Rannazzisi, was there any central body anywhere within DEA organized and formed to review suspicious order reports so that DEA would have a central point of contact to determine whether a particular suspicious order report should be pursued for an investigation by DEA? … A: Not to my knowledge."); 566:7-15 ("Q: Between 2006 and 2015, under Mr. Rannazzisi's leadership, did any DEA field division form a SORs review committee to analyze all SORs, suspicious order reports, received from registrants in that jurisdiction? … A: Not to my knowledge."); 567:20-568:5 ("Between 2006 and 2015 under Mr. Rannazzisi's leadership, did DEA headquarters institute any policy whereby DEA field divisions were required to update DEA headquarters regarding what, if anything, the field division had done to investigate inbound suspicious order reports the field division had received from registrants? A: Not to my knowledge."); 568:20-569:6 ("Q: Between 2006 and 2015, under Mr. Rannazzisi's leadership did DEA have any process that would have allowed the diversion control group at DEA headquarters to know what percentage of suspicious order reports were investigated by the field divisions? … A: Not to my knowledge.").

[159] *See* Press Release, *International Internet Drug Ring Shattered*, DEA (Apr. 20, 2005).

A. Illegal street opioids, most notably heroin and fentanyl, were and are DEA's primary focus during the opioid abuse crisis.

While prescription opioids are part of the opioid abuse crisis, illegal street opioids are the primary concern for DEA. Keith Martin—a longtime DEA agent who is currently an Assistant Special Agent In Charge in Cleveland—agreed that, at least in Ohio, the biggest drug threats are currently heroin, cocaine, fentanyl, carfentanyl, and methamphetamine.[160] Derek Siegle similarly identified heroin and fentanyl as the most significant drug threats in the Ohio HIDTA region.[161]

I recall heroin being a major issue throughout my tenure at DEA. Statistics show that heroin use is a major problem that continues to get worse. Heroin use has grown at an "alarming rate," with the death toll increasing regularly.[162] From 2006 to 2016, heroin-related deaths in the United States have increased from 2,089 to 15,469.[163] Much of this increase is attributable to more recent years: from 2010 to 2016, the rate of heroin-related overdose deaths have increased fivefold.[164]

Drug cartels are to blame for the heroin on our streets. It is common knowledge that much of the heroin distributed in the United States comes from foreign drug cartels, who smuggle it across Mexico's Southwest border.[165] In 2017, 91 percent of the heroin analyzed by DEA originated from Mexico.[166] From 2008 to 2013, the amount of heroin seized at the Southwest border increased over 300 percent.[167] After smuggling it into the United States, Mexican cartels "work with U.S. based gangs and other drug trafficking organizations who distribute the drugs at

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160 *See* Apr. 3, 2019 Dep. of Keith Martin at 186:10-19.
161 *See* Jan. 23, 2019 Dep. of Derek Siegle at 93:16-19.
162 *See* 2018 Nat'l Drug Threat Assessment at 11.
163 *See id.* at 17.
164 *See* Center for Disease Control & Prevention Website: Heroin Overdose Data, *available at* https://www.cdc.gov/drugoverdose/data/heroin.html.
165 *See* Apr. 3, 2019 Dep of Keith Martin at 213:7-214:7; *see also Madden, Justin, Case untangles web of Chinese fentanyl sellers The overseas connection*, Plain Dealer publication Co. (Sept. 3, 2017); 2018 Nat'l Drug Threat Assessment at 18.
166 *See* 2018 Nat'l Drug Threat Assessment at 18.
167 *See* Mar. 26, 2014 Rannazzisi Statement at 6.

the regional and local levels."[168] For example, in the Northeast, street gangs and Dominican drug trafficking organizations work directly with Mexican cartels to distribute heroin locally.[169] Heroin will continue to cause more overdose deaths, due in part to a growing trend of traffickers mixing heroin with fentanyl, which creates a higher risk of overdose.[170]

Illicit fentanyl is the other major illegal street opioid contributing to the opioid abuse crisis. In many ways, it is more concerning than even heroin. Fentanyl is "a powerful synthetic opioid that can shut down breathing in less than a minute." [171] Illicit fentanyl and other synthetic opioids, which are sourced primary from China and Mexico, "are now the most lethal category of opioids used in the United States."[172] In the United States, fentanyl's popularity began to surge at the end of 2013—for each of the next three years, fatal overdoses involving fentanyl rose at an exponential rate, with one study showing a "113 percent average annual increase from 2013 to 2016."[173]

The dark web has facilitated the proliferation of fentanyl and other synthetic opioids.[174] Drug dealers in the United States need not rely on Mexican cartels to obtain synthetic opioids; instead, they can purchase them from Chinese sources anonymously on the dark web using cryptocurrency and receive them through the mail.[175] Due to their relatively high potency, this

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168 *See* 2018 Nat'l Drug Threat Assessment at 11.

169 *See* 2018 Nat'l Drug Threat Assessment at 20.

170 *See id.* at 20.

171 Bebinger, Martha, *Fentanyl-Linked Deaths: The U.S. Opioid Epidemic's Third Wave Begin*s, NPR (Mar. 21, 2019) ("Mar. 21, 2019 NPR Article"), *available at* https://www npr.org/sections/health-shots/2019/03/21/704557684/fentanyl-linked-deaths-the-u-s-opioid-epidemics-third-wave-begins.

172 *See* 2018 Nat'l Drug Threat Assessment at vi**.**

173 *See* Mar. 21, 2019 NPR Article.

174 *See* 2018 Nat'l Drug Threat Assessment at 37; Popper, Natalie *Opioid Dealers Embrace the Dark Web to Send Deadly Drugs by Mail*, New York Times (June 10, 2017), *available at* https://www.nytimes.com/2017/06/10/business/dealbook/opioid-dark-web-drug-overdose.html.

175 *See* DEA Intelligence Report*: The Opioid Threat in the Chicago Field Division* (June 2017) at 17, *available at* https://www.dea.gov/sites/default/files/2018-07/DEA-CHI-DIR-023-17%20The%20Opioid%20Threat%20in%20the%20Chicago%20FD.pdf; Zezima, Katie, *Justice Department fights opioid abuse on dark web and in doctors' offices*, The Washington Post, (August 22, 2018), *available at* https://www.washingtonpost.com/national/justice-department-fights-opioid-abuse-on-dark-web-and-in-doctors-offices/2018/08/22/9c46d374-a630-11e8-a656-943eefab5daf_story html?utm_term=.6ebc97990cff; Popper, Natalie *Opioid Dealers Embrace the Dark Web to Send Deadly Drugs by Mail*, New York Times (June 10, 2017).

purchasing method is more viable for synthetic opioids than heroin—a small parcel or envelope of synthetic opioids can contain a huge number of doses.[176]

Created by Ross Ulbright in 2010, Silk Road was perhaps the most well known marketplace for illicit drugs on the dark web.[177] I became involved in DEA's Silk Road investigation while serving as Deputy Chief Inspector for DEA's Office of Professional Responsibility due to the involvement of Carl Force—a DEA agent who worked undercover on the Silk Road investigation—in a scam involving Silk Road.[178] Among other things, Force was accused of extortion and selling information on the government investigation, and was sentenced to 78 months in prison for his actions.[179] When I became the Special Agent in Charge of the Washington Division, I continued to investigate Silk Road, but on the enforcement side. Although Silk Road was shut down in 2013, similar marketplaces emerged in its absence.[180]

The appeal of fentanyl for drug dealers is clear: they are able to make high profits from its distribution.[181] Since fentanyl can be 50 times more potent than heroin, "smaller amounts translate to bigger profits."[182] And unlike heroin—which requires the harvest of poppies—fentanyl is synthetic combination of chemicals that is more easily supplied.[183]

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176 *See* Popper, Natalie, *Opioid Dealers Embrace the Dark Web to Send Deadly Drugs by Mail*, New York Times (June 10, 2017), *available at* https://www.nytimes.com/2017/06/10/business/dealbook/opioid-dark-web-drug-overdose.html.

177 *See id.*; O'Neill, Patrick, *DEA agent arrested for stealing Silk Road bitcoins also orchestrated murder-for-hire scheme*, The Daily Dot (Mar. 30, 2015), *available at* https://www.dailydot.com/crime/carl-force-silk-road-murder-for-hire/.

178 *See id.*; Mullen, Joe, *Corrupt Silk Road agent Carl Force sentenced to 78 months*, Arstechnica.com (Oct. 19, 2015), *available at* https://arstechnica.com/tech-policy/2015/10/corrupt-silk-road-agent-carl-force-sentenced-to-78-months/; Higgins, Stan, *Rogue Silk Road Agent Carl Force Jailed for 78 months*, Coindesk (Oct. 21, 2015), *available at* https://www.coindesk.com/rogue-silk-road-agent-carl-force-jailed-for-78-months.

179 *See id.*

180 *See* Popper, Natalie, *Opioid Dealers Embrace the Dark Web to Send Deadly Drugs by Mail*, New York Times (June 10, 2017), *available at* https://www.nytimes.com/2017/06/10/business/dealbook/opioid-dark-web-drug-overdose.html.

181 *See* 2018 Nat'l Drug Threat Assessment at 37.

182 *See* Mar. 21, 2019 NPR Article.

183 *See id.*

For drug users, fentanyl is a nightmare. Whether it is ingested on its own or used in combination with other drugs, the increased use of fentanyl is a major reason for the crisis of drug overdose deaths in the United States.[184] Synthetic opioids—a category dominated by fentanyl—are now involved in more deaths than any other illicit drug.[185] Fentanyl is more likely to cause an overdose than heroin because it is more potent and its high fades quicker, which leads to more frequent injections. Statistics suggest that fentanyl is the main reason for the spike in overdose deaths from 2013 to 2016. During this time, death certificates frequently show fentanyl mixed with other drugs (*e.g.*, heroin, cocaine, and semi-synthetic prescription pain medication). If we remove death certificates that mention fentanyl, the spike in overdose deaths is drastically reduced; specifically, cocaine-involved deaths increase 32 percent instead of 110 percent, heroin-involved deaths increase 20 percent instead of 87 percent, and semi-synthetic prescription pain medication-involved deaths increase seven percent instead of 32 percent.[186]

Drug users may also ingest fentanyl without ever intending to do so. Fentanyl is often mixed with other drugs, such as heroin, cocaine, and methamphetamines.[187] In addition, fentanyl and fentanyl analogues are pressed into pill form to imitate prescription medications then sold on the street to unsuspecting purchasers.[188] For example, in April 2018, the Ohio Pharmacists

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184 *See id.* at 27.

185 *See id.*

186 *See* 2018 Nat'l Drug Threat Assessment at 27.

187 *See* Mar. 21, 2019 NPR Article; 2018 Nat'l Drug Threat Assessment at 20; DEA: *US Drug Enforcement Administration Emergency Schedules All Illicit Fentanyls In An Effort To Reduce Overdose Deaths* (Feb. 7, 2018), *available at* https://www.dea.gov/press-releases/2018/02/07/us-drug-enforcement-administration-emergency-schedules-all-illicit.

188 *See* Zezima, Katie, *Counterfeit opioid pills are tricking users -- sometimes with lethal result*, The Washington Post (Nov. 19, 2019), *available at* https://www.washingtonpost.com/national/counterfeit-opioid-pills-are-tricking-users--sometimes-with-lethal-results/2017/11/19/d34edb14-be4b-11e7-8444-a0d4f04b89eb_story.html?utm_term=.d5c11197533c; Press Release, *FDA launches global operation to crack down on websites selling illegal, potentially dangerous drugs; including opioids* (Oct. 23, 2018), *available at* https://www.fda.gov/news-events/press-announcements/fda-launches-global-operation-crack-down-websites-selling-illegal-potentially-dangerous-drugs.

Association warned that counterfeit painkillers were being laced with lethal doses of fentanyl in Ohio and across the United States.[189] Mexican cartels produce some of these counterfeit pills and smuggle them into the United States; but in many cases, drug dealers in the United States order the raw ingredients from China via the dark web and use pill presses set up in private homes—which can churn out thousands of pills per hour—to produce the finished product.[190]

Synthetic opioids—most notably fentanyl and its analogues—create major issues for laboratories and medical examiners. Synthetic opioids are very difficult to detect and can go unreported in medical examiner reports.[191] Indeed, because miniscule amounts can lead to overdose, synthetic opioids are sometimes undetectable during an autopsy.[192] Moreover, to exploit legal loopholes, underground chemists (mostly in China) are constantly creating new fentanyl analogues that are chemically distinct from fentanyl forms already banned by DEA.[193] Laboratories often do not have the ability to search for these new fentanyl analogues.[194] When

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[189] *See* Viviano, JoAnne, *Pharmacists warn against potentially lethal counterfeit pills laced with fentanyl*, The Columbus Dispatch (April 20, 2018), *available at* https://www.dispatch.com/news/20180420/pharmacists-warn-against-potentially-lethal-counterfeit-pills-laced-with-fentanyl.

[190] *See* DEA Intelligence Report*: The Opioid Threat in the Chicago Field Division* (June 2017) at 5, *available at* https://www.dea.gov/sites/default/files/2018-07/DEA-CHI-DIR-023-17%20The%20Opioid%20Threat%20in%20the%20Chicago%20FD.pdf; Zezima, Katie, *Counterfeit opioid pills are tricking users -- sometimes with lethal result*, The Washington Post (Nov. 19, 2019).

[191] *See* "Testimony of Barry K Logan PhD, F-ABFT to the United States Sentencing Commission Public Hearing on Fentanyl, Fentanyl Analogues, and Synthetic Cannabinoids" (Dec. 5, 2017), *available at* https://www.ussc.gov/sites/default/files/pdf/amendment-process/public-hearings-and-meetings/20171205/Logan.pdf.

[192] *See* Joseph, Andrew, *As new opioids spread, coroners face a wave of medical mysteries*, statnews.com (Nov. 22, 2019), *available at* https://www.statnews.com/2016/11/22/opioids-autopsies-medical-examiners/; *see also* Towner, Tiffany, "*We literally can't keep up" — Opioid crisis causing backlog in forensics, where drugs' wild toxicity creates additional danger*, The Register Herald (Nov. 23, 2017), *available at* https://www.register-herald.com/news/we-literally-can-t-keep-up-opioid-crisis-causing-backlog/article_60b3ba76-c559-574b-a4ae-cc8fb417db41 html.

[193] *See DEA: U.S. Drug Enforcement Administration Emergency Schedules All Illicit Fentanyls In An Effort To Reduce Overdose Deaths* (Feb. 7, 2018); *DEA's Plea to Congress: Permanently Ban Fentanyl Substances*, Tribune Content Agency (Apr. 27, 2019), *available at* https://tribunecontentagency.com/article/deas-plea-to-congress-permanently-ban-fentanyl-substances/; *See also* Westlake, Tim, *Congress must move forward on measure dealing with fentanyl*, The Hill (Feb. 13, 2019), *available at* https://thehill.com/blogs/congress-blog/healthcare/429890-congress-must-move-forward-on-measure-dealing-with-fentanyls.

[194] *See* "Testimony of Barry K Logan PhD, F-ABFT to the United States Sentencing Commission Public Hearing on Fentanyl, Fentanyl Analogues, and Synthetic Cannabinoids" (Dec. 5, 2017).

unable to determine a cause of death, samples are typically sent to DEA's special testing laboratory.[195]

This constant influx of novel fentanyl analogues has strained the resources of laboratories and medical examiner offices, creating backlogs.[196] When speaking about this issue, Suzanne Bell, the director of West Virginia University's Department of Forensic and Investigative Science, stated: "We literally can't keep up. Can't keep up with the compounds, can't keep up with the dead and the dying . . ."[197] These backlogs cause slow turnaround at laboratories and medical examiner offices, which not only impact family members seeking information on cause of death, but can also lead to further harm by delaying the identification of and response to new illicit drugs plaguing communities.[198] Indeed, knowledge that a specific drug is plaguing a community can help law enforcement identify the source and lead to the creation of treatment or prevention programs.[199] And, as noted by Greg Cherundolo (chief operations of DEA's Office of Global Enforcement), "[s]adly, these substances are often first discovered when DEA receives reports from local hospitals and coroners in connection with a spate of overdoses."[200] In February 2018, DEA finally responded to the rash of fentanyl analogues by placing all illicit fentanyl analogues on Schedule I on an emergency basis and giving itself the ability to immediately ban new illicit fentanyl

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195 *See* Towner, Tiffany *"We literally can't keep up" — Opioid crisis causing backlog in forensics, where drugs' wild toxicity creates additional danger*, The Register Herald (Nov. 23, 2017).

196 *See id*.; "Testimony of Barry K Logan PhD, F-ABFT to the United States Sentencing Commission Public Hearing on Fentanyl, Fentanyl Analogues, and Synthetic Cannabinoids" (Dec. 5, 2017).

197 *See* Towner, Tiffany, *"We literally can't keep up" — Opioid crisis causing backlog in forensics, where drugs' wild toxicity creates additional danger*, The Register Herald (Nov. 23, 2017).

198 *See id.*

199 *See* A Joseph, Andrew, *As new opioids spread, coroners face a wave of medical mysteries*, statnews.com (Nov. 22, 2019); *see also* "Testimony of Barry K Logan PhD, F-ABFT to the United States Sentencing Commission Public Hearing on Fentanyl, Fentanyl Analogues, and Synthetic Cannabinoids" (Dec. 5, 2017).

200 *DEA's Plea to Congress: Permanently Ban Fentanyl Substances*, Tribune Content Agency (Apr. 27, 2019).

analogues in the future.[201] This temporary measure is still awaiting permanent enshrinement by Congress.[202]

I experienced extensive problems with illicit drugs—including heroin and fentanyl—in my division. In 2016, the District of Columbia, West Virginia, and Maryland ranked first, second, and fifth, respectively, in heroin-involved overdose deaths, and fifth, second, and sixth, respectively, in fentanyl-involved overdose deaths.[203] I recall regular investigations and convictions related to these illicit drugs.[204] In Virginia, for example, we convicted a heroin and fentanyl dealer, Kenneth Stuart (aka "Bones"), who supplied approximately 7,500 to 25,000 individual doses from March to December 2016.[205] Marking his heroin and fentanyl with brand names like "King of Death," Stuart showed a callous disregard to the victims of his actions; upon learning of a death caused by his fentanyl, Stuart laughed, and remarked, "another one bit the dust."[206] As explained in more detail below, other than the products they sold, little separates heroin and fentanyl dealers from pill mill or internet pharmacy doctors who prescribe prescription opioids without legitimate need.

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201 See *id.*

202 *See id.*; *see also* Westlake, Tim, *Congress must move forward on measure dealing with fentanyl*, The Hill, (Feb. 13, 2019).

203 *See* 2018 Nat'l Drug Threat Assessment at 29.

204 *See, e.g.*, Press Release: *Portsmouth Heroin Dealer Sentenced to 25 Years*, U.S. Attorney's Office, Eastern District of Virginia (Apr. 4, 2018), *available at* https://www.justice.gov/usao-edva/pr/portsmouth-heroin-dealer-sentenced-25-years; Press Release: *Maryland Man Sentenced to 20 years for Drug Trafficking*, U.S. Attorney's Office, Eastern District of Virginia (Mar. 23, 2018), *available at* https://www.justice.gov/usao-edva/pr/maryland-man-sentenced-20-years-drug-trafficking; Press Release: *State's Attorney Mosby Joins Local, State, and Federal Investigators to Announce Drug Bust and Indictment of Criminal Organization Leaders*, Office of the State's Attorney, Baltimore City, Maryland (Mar 14, 2018), *available at* https://www.stattorney.org/media-center/press-releases/1435-state-s-attorney-mosby-joins-local-state-and-federal-investigators-to-announce-drug-bust-and-indictment-of-criminal-organization-leaders.

205 *See* Press Release: *"King of Death" Heroin Supplier Sentenced to Life in Prison*, U.S. Attorney's Office, Eastern District of Virginia (Apr. 4, 2018), *available at* https://www.justice.gov/usao-edva/pr/king-death-heroin-supplier-sentenced-life-prison.

206 *See id.*

B. Illicit sources for prescription opioids—such as pills mills, internet pharmacies, and doctor shopping—were and are a major cause of the opioid abuse crisis.

Illicit sources for prescription opioids have been a major cause of the opioid abuse crisis. Diversion can occur through a variety of methods. In August 2011, GAO listed common sources of diversion:

> "Diversion can occur as a result of illegal or improper prescribing, prescription forgery, pharmacy thefts, or "doctor shopping" where an individual—who may or may not have legitimate medical needs—goes to several doctors to obtain a prescription from each doctor. Diversion can also occur through illegal sales of controlled substances, such as drugs sold by physicians, patients, or pharmacists, as well as individuals obtaining these substances without a valid prescription through Internet pharmacies or pain clinics."[207]

As this passage indicates, diversion can be traced back to several sources: improper prescribing, prescription forgery, theft, doctor shopping, internet pharmacies, and rogue pain clinics (aka "pill mills"). In his testimony before the Energy and Commerce Committee on December 13, 2005, Rannazzisi listed similar sources of diversion:

> "A quick search on the Internet reveals thousands of sites offering pharmaceutical controlled substances for sale. The sale of these substances over the Internet is only one way that users illegally acquire pharmaceuticals. The DEA has also investigated cases where prescriptions have been forged; pharmacies have been robbed: unscrupulous doctors have operated "pill mills" that essentially sell prescriptions or drugs after perfunctory or non-existent medical examinations; or pharmaceuticals have been smuggled into the United States. However they are acquired, the illegal use of pharmaceuticals is one of the fastest growing forms of drug abuse."[208]

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[207] *See* 2011 GAO Report at 2; *see also Wartell, Julie, Prescription Drug Fraud Misuse*, Community Oriented Policing Services, USDOJ a*vailable at* *https://popcenter.asu.edu/sites/default/files/sites/default/files/problems/pdfs/prescription_fraud.pdf* at 6-7 (A report supported by an award from the U.S. Department of Justice, discussed the "significant and growing problem" of prescription drug fraud and misuse, and provided a similar list of sources for this conduct; namely, prescription forgery, doctor shopping, obtaining illegally prescribed drugs via the internet, acquiring drugs prescribed to family or friends, and altering prescriptions to increase the quantity.)

[208] *See* Written Testimony of Joseph T. Rannazzisi, Acting Deputy Assistant Administrator, Office of Diversion Control, DEA, Before The U.S. House of Representatives Energy & Committee (Dec. 13, 2005) [US-DEA-00002454] at 1-2.

I recall internet pharmacies as a major issue early on. In the mid-2000s, DEA invested a substantial amount of resources to combat rogue internet pharmacies.[209] For example, I was part of a year-long investigation called Operation "Cyber Chase," which targeted international internet pharmaceutical traffickers operating in the United States and abroad, and led to twenty arrests.[210] Kyle Wright testified that internet pharmacies took up a "great deal" of DEA's time and agreed that, by 2005, they were DEA's biggest problem.[211] These internet-based traffickers would provide controlled substances without establishing a legitimate doctor-patient relationship.[212] Despite often posing as legitimate pharmacies, rogue internet pharmacies provide no "face-to-face medical examination, no tests, no drug interaction screening, and no follow-up care."[213]

Although they were a major source of diversion from 2006 to 2009, domestic rogue internet pharmacies were virtually eliminated after the implementation of the Ryan Haight Act.[214] In the void created by the closure of internet pharmacies, rogue pain clinics or "pill mills" became the next major source for obtaining prescriptions without legitimate medical need.[215] A pill mill is a "physician's office, clinic, or health care facility that routinely engages in the practice of prescribing and dispensing controlled substances without a legitimate medical purpose . . ."[216] Like street drug dealers, pill mills operate on a "cash only" basis.[217]

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209 *See* Dec. 19, 2018 Energy & Commerce Committee Report at 24.
210 *See* Press Release, *International Internet Drug Ring Shattered*, DEA (Apr. 20, 2005).
211 *See* Feb. 28, 2019 Dep. of Kyle Wright at 89:2-21.
212 *See* 2011 GAO Report at 2.
213 *See* Written Testimony of Joseph T. Rannazzisi, Acting Deputy Assistant Administrator, Office of Diversion Control, DEA Before The U.S. House of Representatives Energy & Committee (Dec. 13, 2005) [US-DEA-00002454] at 1-2.
214 *See* Statement for the Record of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA Before the U.S. House of Representatives House & Energy Committee Entitled "*Warning: The Growing Danger of Prescription Drug Diversion*" (Apr. 14, 2011) ("Apr. 14, 2011 Rannazzisi Statement") [US-DEA-00020506] at 9.
215 *See* Mar. 26, 2014 Rannazzisi Statement.
216 *See U.S. vs. Blume*, S.D. WV, 5:18-cr-00026, Dkt. 4, at 2.
217 *See* Rigg, Khary, *Prescription Drug Abuse & Diversion: Role of the Pain Clinic*, J Drug Issues. 2010; 40(3): 681–702, *available at* https://www ncbi nlm nih.gov/pmc/articles/PMC3030470/.

Diversion has also occurred through less elaborate means. Prescription opioids are stolen by family or friends of the prescription holders.[218] And doctor shopping—when a patient obtains prescriptions from several doctors without the prescribers' knowledge of the other prescriptions[219]—is another common method of diversion.[220]

DEA eventually invested considerable resources to stem the flow of prescription opioids diverted through these sources. Most notable was the use of Tactical Diversion Squads, which pool DEA resources with state and local law enforcement. Tactical Diversion Squads are responsible for investigating the sources of diversion discussed above, including doctor shoppers and pill mills. DEA began investing heavily in Tactical Diversion Squads, leading to a significant increase in criminal and administrative cases.[221]

I remember encountering the same illicit sources in the states under my purview. In West Virginia, for example, the primary methods of diversion were "illegal sale and distribution by health care professionals and workers, 'doctor shopping' (going to a number of doctors to obtain prescriptions for a controlled pharmaceutical), employee theft, forged prescriptions, and the Internet." [222] These diverted pharmaceuticals are sold by "independent drug trafficking organizations," which are particularly active in West Virginia due to the high potential for profit—illicit pharmaceuticals can be sold in West Virginia at prices two to three times higher than other

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[218] *See* Apr. 14, 2011 Rannazzisi Statement at 10.

[219] *See Doctor Shopping Laws*, Public Health Law, Office for State, Tribal, Local & Territorial Support, CDC (Sept. 28, 2012), *available at* https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf.

[220] *See* Remarks by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA Before the U.S. Senate Judiciary Committee regarding "*Rogue Online Pharmacies: The Growing Problem of Internet Drug Trafficking*" (May 17, 2007) [US-DEA-00005325] at 2.

[221] *See* Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA, Before The Caucus On International Narcotics Control, United States Senate at a Hearing Entitled Responding To The Prescription Drug Abuse Epidemic (July 18, 2012) [US-DEA-00019479] at 8; MEDIA ADVISORY: DEA to Host Conference on the Formation of a Tactical Diversion Squad in Clarksburg, West Virginia (May 19, 2016), *available at* https://www.dea.gov/press-releases/2016/05/19/media-advisory-dea-host-conference-formation-tactical-diversion-squad.

[222] *See* Dec. 19, 2018 Energy & Commerce Committee Report at 48-49.

states.[223] Although West Virginia certainly had its own pill mills, a lot of its diverted controlled substances came from out-of-state sources, such as Florida pill mills.[224] West Virginia was not the only state flooded with diverted controlled substances from Florida pill mills. As noted by U.S. Senator Sherrod Brown (D-OH), this pipeline from Florida supplied Ohio and other states along the I-75 corridor.[225]

I can recall several examples of illegitimate prescribing and dispensing while I was at DEA. In West Virginia, the *mayor* of Bridgeport—who worked as a pharmacist—dispensed prescription painkillers illegitimately.[226] As I state in a June 3, 2014 news article, we poured considerable resources into this investigation: "Over approximately three years, Blount illegally dispensed over 11,000 oxycodone and oxymorphone pills . . . [the] arrests are the culmination of a ten month investigation . . ."[227] Unfortunately, this case is not an isolated example. Indeed, it was an earlier case against a West Virginia doctor—whose improper prescribing may have led to more than 10 overdose deaths—that led to the investigation of the Bridgeport mayor.[228] Hope Pain Clinic is an example of an especially large pill mill operation in West Virginia; beginning in November 2010, it illegitimately dispensed pain medication from several West Virginia locations, until we shut it down in June 2015.[229] I was also involved in a civil settlement with Judy's Drug Store—a West Virginia pharmacy that dispensed prescription opioids without legitimate medical need, which

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223 *See id.* at 49.

224 *See id.* at 4, 50.

225 *See* Press Release: *With Private Funds Offered to Crack Down on Florida Pill Mills that Supply to "Oxy-Express", Sen. Brown Tells Florida Gov. "No More Excuses"*, Sherrod Brown Senator for Ohio, (Mar. 11, 2011), *available at* https://www.brown.senate.gov/newsroom/press/release/with-private-funds-offered-to-crack-down-on-florida-pill-mills-that-supply-to-oxy-express-sen-brown-tells-florida-gov-no-more-excuses.

226 *See* Payne, Aaron, *Bridgeport Mayor Arrested on Federal Drug Charges*, Wvmetronews.com (June 3, 2014), *available at* http://wvmetronews.com/2014/06/03/bridgeport-mayor-arrested-on-federal-drug-charges-involving-painkillers/.

227 *See id.*

228 *See id.*; *Doctor Sentence to 5 years for Illegal Pain*, The Associated Press (May 12, 2015), *available at* https://www.wvpublic.org/post/doctor-sentenced-5-years-illegal-pain-prescriptions#stream/0.

229 *See U.S. vs. Blume*, S.D. WV, 5:18-cr-00026, Dkt. 4, at 2.

came to our attention after the arrest of a West Virginia doctor who wrote many of the unnecessary prescriptions filled by Judy's.[230]

My experience with pill mills, illegitimate prescribing, and illegitimate dispensing was by no means confined to West Virginia. As Special Agent in Charge of the Washington Division Office, I encountered such conduct in all the regions under my watch.[231] In Virginia, one doctor that we sentenced to 30 years for dispensing fraudulent oxycodone prescriptions was described by an expert as "a one-man opioid epidemic."[232] In June 2013, when announcing the guilty plea of a Maryland pharmacist who dispensed pain medication illegitimately, I remarked that it is such "illicit activities which fuel this problem" of prescription pharmaceutical abuse.[233] Illegitimate prescribing and dispensing were not the only issues in my division. I also recall encountering pharmacy thefts and prescription forgery in my region,[234] which contributed to the flow of

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[230] *See Petersburg pharmacy settles to end investigation into federal drug charges*, MetroNews (June 4, 2014), *available at* http://wvmetronews.com/2014/06/04/petersburg-pharmacy-settles-to-end-investigation-into-federal-drug-charges/.

[231] *See, e.g.*, Press Release: *Waldorf Man Sentenced To 4 Years In Prison For Running Oxycodone Pill Mill*, U.S. Attorney's Office, District of Maryland (Apr. 24, 2018), *available at* https://www.justice.gov/usao-md/pr/waldorf-man-sentenced-4-years-prison-running-oxycodone-pill-mill; Press Release: *Nurse-Practitioner Found Guilty of Federal Charges*, U.S. Attorney's Office, District of Columbia (Aug. 10, 2017), *available at* https://www.justice.gov/usao-dc/pr/nurse-practitioner-found-guilty-federal-charges-illegally-distributing-oxycodone-and; Press Release: *Doctor Sentenced to 30 Years for Oxycodone Distribution Conspiracy*, U.S. Attorney's Office, Eastern District of Virginia (Dec. 19, 2017), *available at* https://www.justice.gov/usao-edva/pr/doctor-sentenced-30-years-oxycodone-distribution-conspiracy.

[232] *See* Press Release: *Doctor Sentenced to 30 Years for Oxycodone Distribution Conspiracy*, U.S. Attorney's Office, Eastern District of Virginia (Dec. 19, 2017), *available at* https://www.justice.gov/usao-edva/pr/doctor-sentenced-30-years-oxycodone-distribution-conspiracy.

[233] *See* Press Release: *Hagerstown Pharmacist Pleads Guilty to Health Care Fraud For Improperly Billing Medicare And Medicaid*, US. Attorney's Office, District of Maryland (June 14, 2013), *available at* https://www.justice.gov/usao-md/pr/hagerstown-pharmacist-pleads-guilty-health-care-fraud-improperly-billing-medicare-and.

[234] *See* Press Release: *Former Medical Assistant Pleads Guilty to Distributing Oxycodone*, U.S. Attorney's Office, Eastern District of Virginia (May 22, 2018), *available at* https://www.justice.gov/usao-edva/pr/former-medical-assistant-pleads-guilty-distributing-oxycodone; Press Release: *16 Charged in Three Indictments In Connection With A Conspiracy To Burglarize 47 Pharmacies In Three States And Trafficking Stolen Firearms In Philadelphia*, U.S. Attorney's Office, Eastern District of Pennsylvania (Nov. 14, 2007), *available at* https://www.dea.gov/sites/default/files/divisions/phi/2007/phila111407p.html.

illegitimate pain medication on our streets. The illegal conduct described above—not the legitimate sale of prescription opioids—was a significant cause of the opioid abuse crisis.

Karl C. Colder

Date: May 31, 2019

Karl C. Colder

EXHIBIT A - CURRICULUM VITAE

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EXECUTIVE PROFILE

Consummate leader able to unite diverse, coalitions, stakeholders, and multi-cultural groups to one accord; unique talent for encouraging true collaboration and cohesiveness.
Sought to head priority initiatives, training and development of new programs; maintain access to influential corporate, federal, state and local government executives and networks.
Ideal leader and articulate communicator capable of handling delicate and politically sensitive issues.
Exceptional liaison and interpersonal skills with a specific emphasis on establishing and enhancing relationships with partners.
Directs and promotes sound business and operational principles to incorporate new vision and move organizations forward.
Holds Top Secret (TS) security clearance.

CORE EXECUTIVE QUALIFICATIONS

Interagency Relations	Legislation and Policy Formulation	Crisis Management and Preparedness
Financial Management/Contracting	Media & Public Relations	Change & Turnaround Management
Organizational Leadership	Strategic /Tactical Planning	Budget Planning, Development & Control
Internal Investiga ions	Staff Development	Government & International Relations
Security Program Operations	Recruiting, Staffing & Training	Program Development / Management
Productivity Improvement	International Chemical Initiatives	Strategic Alliances & Partnerships
Influencing Decision-Makers	Team Building	Problem & Conflict Resolution
EEO Programs	Implicit Bias Training	Compliance Management

Summary of Executive Qualifications and Experience:

Thirty-two years of career leadership and professional investigative experience with the U.S. Department of Justice, Drug Enforcement Administration (DEA) marked with steady promotions to lead U.S. Drug Policy and oversee complex domestic and foreign investigations. As Special Agent in Charge, I was responsible for managing the productivity and leveraging budgetary strategies for a Division consisting of more than 500 personnel comprised of Special Agents, Task Force Officers, Intelligence Analysts, Diversion Investigators, Security Specialists, IT Specialists, contract employees, and support staff located in 13 facilities within a four-state region. This involved managing 5 highly motivated Assistant Special Agents in Charge, a Diversion Control Program Manager, and a Field Intelligence Manager assuming the responsibility of 60 supervisors under their command to ensure they were leveraging all available resources and operations to the maximum effect. Due to the wide latitude in how they perform their duties, it was vitally important to ensure I provided them with a strategic plan along with their performance work plans and ensured their work was aligned with both plans. The strategies for effectively investigating criminal organizations must constantly evolve or risk losing effectiveness. Agility and adaptability are critical to DEA's success due to changing drug trends and strategies. Ultimately it was my job to effectively manage a large group of highly motivated individuals and focus them on the accomplishment of mutually desired goals by leveraging their strengths and minimizing their weaknesses. It was also vital

that I maintained outstanding relationships with law enforcement, prevention, medical/pharmaceutical professionals, community leaders, and legislators by serving in leadership roles on multi-jurisdictional executive committees and task forces to leverage DEA's capacity in building coalitions. I directed the coordination of all training to law enforcement agencies and professional stakeholders. I also directed all media, public affairs, and drug prevention initiatives.

As the Acting Chief Inspector, I managed the operations of the DEA office of Security Programs responsible for the physical, personnel, and information security operations. I am able to identify and effectively mitigate or manage, at an early stage, any developments that may threaten the resilience and continued survival of DEA facilities. I managed the close coordination of all functions within the Agency that are concerned with security, continuity and safety. As the DEA Deputy Chief Inspector, I was charged to investigate allegations of misconduct against DEA Employees, task force officers, and contract employees. I was responsible for managing the productivity of 6 highly motivated Senior Inspectors assuming the responsibility of 24 Inspectors under their command to conduct domestic and international internal investigations. I ensured all available resources were leveraged to the maximum effect, and ensured all inspectors received the necessary training in policy and procedure to enhance their capacity for maximum success. I conceived, planned, implemented, and communicated effective policies and procedures that reduced the impact of misconduct. The ability to navigate my way through in the components of information security, physical security, personnel security, risk management, human resources, and EEO was essential in developing the cognitive strengths to implement strategic plans, guidance, and training to employees at all levels. Due to antiquation and the lack of storage capacity in the OPR integrity database, I served as the champion for the development of a new database for personnel integrity checks, internal investigations, and an early warning system.

U.S. Department of Justice, Drug Enforcement Administration

Special Agent in Charge — February 2013 - May 2018
Washington Field Division, Washington, DC

- Commanded DEA's Washington Division Office. Headquartered in Washington, DC, I directed all DEA operations throughout the states of Maryland, West Virginia, Virginia, and the District of Columbia.
- Managed a budget for the Washington Division Office; comprised of more than 500 personnel to include Special Agents, Task Force Officers, Intelligence Analysts, Diversion Investigators, Security Specialists, IT Specialists, and support staff located in 13 facilities within the four-state region. Displayed capability to leverage administrative and enforcement operations with limited resources.
- Drafted proposals to strategically leverage upgrades in personnel and facilities in West Virginia, Virginia, Maryland, and the District of Columbia with limited resources to build effective enforcement and administrative teams.
- Managed the Division Diversion Program responsible for registering, monitoring and auditing medical practitioners, pharmacists, and drug manufacturers. I was responsible for managing the productivity and leveraging budgetary strategies for the program.
- Prepared and executed strategic field management and strategic intelligence plan. Increased foreign liaison effort and led multi-agency U.S. delegations to South America to collaborate with counterparts on intelligence information, host country operation briefings, and to ensure investigative coordination and secure continued cooperation.
- I was a representative for DEA on federal, state, and local executive boards, committees, and task forces within the region to include the Maryland, Virginia, and West Virginia Chiefs of Police and Sheriffs.
- Provided training, education and technical assistance for coalition leaders, community teams, substance abuse prevention and treatment stakeholders, and state pharmacy boards to enhance their capacity to leverage law enforcement resources.
- Forged relationships with representatives from coalitions and law enforcement task force initiatives, legislators, and other federal, state, and local partners to develop drug law enforcement and prevention strategies and leverage our capacity in the community.
- Provided oversight of the Division's Public Information Officer Program to actively promote public awareness programs enhancing national and international recognition of agency's mission and

accomplishments; Spearheaded campaign to host the DEA's Traveling Drug Exhibit, "Target America; Cost and Consequences" at the Maryland Science Center in Baltimore, MD and Leesburg, Virginia.
United with leaders to Develop Effective Strategies to Address the West Virginia Opioid Epidemic through the DEA 360 strategy.
Served as direct contact to the media and conducted numerous media interviews, public speeches, and public relations encounters.
Managed all enforcement and administrative activity involving Diversion Control in the Division's area of responsibility.
Served as Chairman of the Appalachia and Baltimore Washington ONDCP High Intensity Drug Trafficking Area (HIDTA) Executive Boards.
Appointed to the Virginia and Maryland Governor's Task Force for Opioids and Prescription Drugs.
Served as the chair, vice-chair and member of DEA's Diversity Committee (started in 2010); Led the development of the DEA's Diversity Management Plan, and was responsible for reporting and briefing the agency's management plan and accomplishments to the Attorney General.
Provided briefings to federal, state and local elected officials, professional associations, and corporate representatives on current drug trends and enforcement strategies.
Established Citizens Academies in Baltimore, MD and Richmond, VA to complement Citizens Academy Program in Washington, DC. Built coalitions with business, clergy and community leaders.
Represented the Drug Enforcement Administration at Joint Terrorism Task Force Executive sensitive briefings in SCIF environment.
Worked in SCIF environment to conduct internal investigations and major criminal domestic and international investigations.

Deputy Chief Inspector — April 2009 - February 2012
DEA Headquarters Inspections Division,
Office of Professional Responsibility, Arlington, VA

Led all domestic and foreign administrative and criminal internal affairs program operations at the DEA.
Prepared and executed strategic plan for the Office of Professional Responsibility; led 7 GS-15 level managers.
Coordinated internal investigations with the DOJ Office of Inspector General and other federal, state and local agencies.
Provided guidance to agency Senior Executives, employees and trainees concerning DEA policy, procedures, and the disciplinary process.
Coordinated investigative activities with the DEA Offices of Chief Counsel, Human Resources, Security Programs, Board of Professional Conduct, and Deciding Officials for adjudication of all DEA internal investigations.
Champion for the development of DEA's integrity database system as a replacement to an antiquated system.
Developed an "Early Warning System" as a compliance tool for managers to identify potential misconduct by employees.
Provided monthly, quarterly and annual internal investigative reports to the DEA Administrator.
Directed enforcement, regulatory compliance, financial and technical operations; conceived and enhanced innovative initiatives that enhanced personnel and physical security programs to comply with DOJ and DEA policies and procedure.

Assistant Special Agent in Charge — June 2005 - April 2009
Philadelphia Field Division, Philadelphia, PA

Served the DEA Special Agent in-Charge by assisting with organization, planning, coordination and establishment of Division priorities and programs.
Led multiple enforcement and Task Force Group Supervisors in Philadelphia; and, Tactical Diversion Squads throughout the Division comprised of 200 Federal, State, and Local law enforcement personnel and support staff in pursuit of transnational criminal organizations.

Oversaw the Administrative Support and managed Fiscal Operations and budget for the Division.
Organization, planning, coordination and implementation of operational priorities, personnel placement and related human capital matters, and programs.
Served the Special Agent in-Charge in the oversight of the Global and Domestic enforcement operations, programs, and operational priorities.
Approved funds for enforcement operations, field investigations, travel, award payments, and other fund transfers.
Served as direct contact with community-based organizations; professional associations; business leaders; and elected officials.
DEA Explorer Scout Program Facilitator

Senior Inspector/Inspector — January 2002 - June 2005
Newark Field Office, Office of Professional Responsibility
Newark, NJ and DEA Headquarters, Arlington, VA

Led all DEA administrative and criminal internal affairs program operations in the northeast region (MA, NY, NJ, PA, DE, and the New England States); Prepared and executed the strategic plan for the office and led 4 GS-14 Inspectors.
Coordinated investigative activities with the US Department of Justice Office of the Inspector General; the DEA Offices of Chief Counsel, Human Resources, Security Programs, Board of Professional Conduct, and Deciding Officials for adjudication of all allegations of misconduct concerning DEA employees, contract employees, and task force officers.

Resident Agent in Charge/Special Agent — January 1986 - June 2002
Dallas Field Division, Fort Worth Resident Office, Fort Worth, TX
Philadelphia Field Division, Caribbean Field Division, St. Croix, USVI

Manager of two GS-14 Special Agents and one Task Force Supervisor in the Fort Worth Resident Office.
Led a multi-group of DEA Special Agents, police officers, detectives, and sheriff's deputies employed to conduct interdiction investigations and enforce drug laws at the Dallas/Fort Worth (DFW) International Airport.
Established bus and railway interdiction initiative as an enhancement to the airport interdiction efforts in Dallas and Fort Worth, TX.
Established relationships with the U.S. Postal Service and other private mail and parcel services to leverage maximum parcel interdiction efforts.
Led 2 state and local task force groups responsible for conducting complex domestic and international investigations in Fort Worth.
Supervised 3 Diversion Investigators to conduct investigations to uncover suspected sources of diverted pharmaceuticals and regulated chemicals from the legitimate channels in which they are manufactured, distributed and dispensed.
Led the establishment of the St. Croix Resident Office as the Senior Agent assigned to the post.
Directed the initiation of the High Intensity Drug Trafficking Area Task Force in St. Croix; led 2 Special Agents and 3 Virgin Islands Police Department Task Force Officers.
Conducted complex domestic and international trans-shipment and conspiracy cases for prosecution by the U.S. Attorney's Office.
Provided expert witness testimony before the Federal Grand Jury and U.S. District Court.
Managed and directed confidential sources of information. Performed undercover activities.
Provided court testimony for grand jury proceedings and criminal trials.
Assigned as Field Training Agent for new agents assigned to the Philadelphia Field Division.
Served as Recruitment, Training Coordinator, and Demand Reduction Coordinator for Philadelphia Field Division.
DEA Explorer Scout Program Counselor.

PRE-DEA WORK EXPERIENCE:

Alcohol and Drug Intake Counselor **1985 - 1986**
Philadelphia Diagnostic Rehabilitation Center

Conducted intake process and coordinated the administration of treatment programs for individuals suffering from drug and alcohol abuse issues.

POST-DEA WORK EXPERIENCE:

President **May 2018 - Present**
Colder Allied Consulting, LLC

Provide professional consulting services, with a specialization in program performance and information management support.
Assist companies in maintaining successful working relationships with clients in the private and federal sectors.
Help companies and non-profits improve their performance and navigate their technology, platforms, and analytical strategies.
Collaborate with clients (including communities, health providers, law enforcement, non-profit organizations, and other federal, state, and local agencies) and offer innovative and evidence-based intervention approaches to prevent and reduce substance use and promote peoples' health and well-being.

EDUCATION:

M.A. Human Resources Development and Training, Seton Hall University, South Orange, NJ 2009
B.A. Social Relations/Criminal Justice, Cheyney State University, Cheyney, PA 1984
B.A. Political Science, Cheyney State University, Cheyney, PA 1983

LEADERSHIP TRAINING:

Leadership Dynamics of Supervisory Behavior, Seton Hall University
Executive Leadership Institute, Johns Hopkins University
Grass Roots Executive Leadership, Johns Hopkins University
Executive Leadership Institute, University of Virginia
Executive Writing Analysis Course
Executive Communications Workshop, University of Phoenix
Management Assessment, University of Phoenix
Policy and Analysis in Administration
Instructor Development
Management Leadership Training (Gettysburg)
Anti-Defamation League Advanced Training School
HR Reasonable Accommodation Training
EEO Special Emphasis Training
Operation Jetway Interdiction Training

Technical Skills: Knowledge of Title 21, U.S. Code (criminal) and Title 21, Code of Federal Regulations (Food and Drugs); Proficient in Microsoft Office Suite including Word, PowerPoint, Excel and Outlook.

Professional and Community Civic Affiliations: Association of Federal narcotics Agents (AFNA), Past National President of the National Association of Black Narcotic Agents (NABNA), and a member of the National Association of Black Law Enforcement Executives (NOBLE). Metropolitan Washington Council of Governments Substance Dependency Program Executive Planning Committee Chairman, ONDCP Baltimore/Washington and Appalachia High Intensity Drug Trafficking Area Task Force Executive Committee Chairman, West Virginia Council of Churches Substance Abuse Task Force, Episcopal Church Province 3 Opioid Abuse Task Force Co-Chair, and the Virginia Governor's Task Force for opioids and Heroin Abuse.

Member of numerous fraternal, faith based, civic, community, and youth athletic associations /organizations. Member of ASIS International

REFERENCES: Professional and social character references are available upon request

EXHIBIT B - DOCUMENTS CONSIDERED

I. Documents Cited in Body of Report

Referenced in footnotes throughout report.

II. Deposition Transcripts and Exhibits

- 2019-01-23 Derek Siegle Final Deposition Transcript and Exhibits 1-8
- 2019-01-25 Keith Martin Final Deposition Transcript and Exhibits 1-9
- 2019-01-30 Patrick Leonard Final Deposition Transcript and Exhibits 1-8
- 2019-02-28 & 2019-03-04 Kyle Wright Final Deposition Transcripts and Exhibits 1, 2, 4, 5, 9-12, 14, 17, 20, 26, 27, 28, 29 30-51
- 2019-03-15 Demetra Ashley Deposition Transcript and Exhibits 1-26
- 2019-03-29 Lori Baker-Stella Final Deposition Transcript and Exhibits 1-6
- 2019-01-30 & 2019-03-29 John Prince Final Deposition Transcripts and Exhibits 1-27
- 2019-04-11 Stacy Harper-Avilla Final Deposition Transcript and Exhibits 1-18
- 2019-04-26 & 2019-05-15 Joseph Rannazzisi Final Deposition Transcripts and Exhibits 1-14
- 2019-04-17, 2019-04-18 & 2019-05-17 Thomas Prevoznik Final Deposition Transcripts and Exhibits 1-60

III. Expert Reports

- 2019-04-15 Lacey Keller Expert Report
- 2019-04-15 Craig McCann Second Supplemental Expert Report
- 2019-04-15 James Rafalski Expert Report
- 2019-04-15 Stephen Schondelmeyer Expert Report
- 2019-04-15 Seth Whitelaw Expert Report

IV. Pleadings

- CA-State, Fifth Amended Complaint, ECF 1062 (Mar. 23, 2018).

- OH-Cleveland, Second Amended Complaint (May 25, 2018).

- OH-Summit, Complaint (Dec. 20, 2017).

V. Written Discovery

- MDL-Opiate, Allergan Finance, LLC's Objections and Responses to Plaintiffs' First Set of Interrogatories (May 24, 2018).

- MDL-Opiate, Plaintiffs Summit County, Cuyahoga County, City of Akron and City of Cleveland's Supplemental Response and Objections to the Manufacturer Defendants' First Set of Interrogatories (Jan. 18, 2019).

- MDL-Opiate, Summit County, Cuyahoga County, and the Cities of Akron and Cleveland, Ohio Plaintiffs' Responses and Objections to Manufacturer Defendants' Fourth Set of Interrogatories (Mar. 4, 2019).

- OH-Cleveland, Manufacturer Defendants' First Set of Requests for Production to Plaintiff City of Cleveland (Apr. 16, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Responses to Manufacturer Defendants' First Set of Requests for Production (May 16, 2018)

- OH-Cleveland, Plaintiff City of Cleveland's Responses to Manufacturer Defendants' First Set of Requests for Production (May 16, 2018).

- OH-Cleveland, Manufacturer Defendants' Second Set of Requests for Production to Plaintiff City of Cleveland (July 3, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Responses and Objections to Manufacturer Defendants' Second Set of Requests for Production (Aug. 2, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Replacement Supplemental Responses and Objections to Manufacturer Defendants' Interrogatories (Mar. 18, 2019).

- OH-Cleveland, Manufacturer Defendants' First Set of Interrogatories to Plaintiff City of Cleveland (Apr. 25, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Responses to Manufacturer Defendants' First Set of Interrogatories (May 25, 2018).

- OH-Cleveland, Manufacturer Defendants' Second Set of Interrogatories to Plaintiff City of Cleveland (June 5, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (July 2, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Responses and Objections to Manufacturer Defendants' Second Set of Interrogatories (July 5, 2018).

- OH-Cleveland, Plaintiffs the County of Cuyahoga, Ohio and the State of Ohio Ex Rel. Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Second Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (Aug. 17, 2018).

- OH-Cleveland, The City of Cleveland's Responses and Objections to Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories and Exhibits (Nov. 2, 2018).

- OH-Cleveland, Plaintiff City of Cleveland's Supplemental Responses and Objections to Interrogatories Nos. 11 and 18 of Manufacturer Defendants' Second Set of interrogatories (Nov. 8, 2018).

- OH-Cleveland, Plaintiffs City of Cleveland and county of Cuyahoga's Amended Responses and Objections to Manufacturer Defendants' Interrogatory No. 27 (Nov. 27, 2018).

- OH-Cleveland, Manufacturer Defendants' Third Set of Interrogatories to Plaintiff City of Cleveland (Nov. 29, 2018).

- OH-Cleveland, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Supplemental Objections and Responses to Manufacturer Defendants' Interrogatory Nos. 28/29 (Dec. 28, 2018).

- OH-Cleveland, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Responses to Manufacturer Defendants' Third Set of Interrogatories (Dec. 31, 2018).

- OH-Cleveland, Manufacturer Defendants' Fourth Set of Interrogatories to Plaintiff City of Cleveland and Exhibit A (Jan. 19, 2019).

- OH-Cleveland, Manufacturer Defendants' Amended Interrogatory No. 33 to Plaintiff City of Cleveland (Feb. 26, 2019).

- OH-Cleveland, Plaintiff City of Cleveland's Supplemental Responses and Objections to Manufacturer Defendants' Interrogatories (Mar. 4, 2019).

- OH-Cuyahoga, Manufacturer Defendants' First Set of Requests for Production to Plaintiff City of Cleveland (Apr. 16, 2018).

- OH-Cuyahoga, Plaintiffs the County of Cuyahoga, Ohio and State of Ohio Ex Rel, Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Initial Responses and Objections to Manufacturer Defendants' First Set of Requests for Production (May 16, 2018).

- OH-Cuyahoga, Manufacturer Defendants' Second Set of Requests for Production to Plaintiff County of Cuyahoga (July 3, 2018).

- OH-Cuyahoga, Plaintiffs The County of Cuyahoga, Ohio and State of Ohio Ex Rel, Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Initial Responses and Objections to Manufacturer Defendants' Second Set of Requests for Production (Aug. 2, 2018).

- OH-Cuyahoga, Cuyahoga County's Replacement Supplemental Responses and Objections to Manufacturer Defendants' Interrogatories (Mar. 19, 2019).

- OH-Cuyahoga, Manufacturer Defendants' First Set of Interrogatories to Plaintiff County of Cuyahoga (Apr. 25, 2018).

- OH-Cuyahoga, Plaintiffs The County of Cuyahoga, Ohio and the State of Ohio Ex Rel. Prosecuting Attorney of Cuyahoga County, Michaels C. O'Malley's Initial Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (May 25, 2018).

- OH-Cuyahoga, Manufacturer Defendants' Second Set of Interrogatories to Plaintiff County of Cuyahoga (June 5, 2018).

- OH-Cuyahoga, Plaintiffs the County of Cuyahoga, Ohio and the State of Ohio Ex Rel. Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (June 12, 2018).

- OH-Cuyahoga, Plaintiffs the County of Cuyahoga, Ohio and the State of Ohio Ex Rel. Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Responses and Objections to Manufacturer Defendants 'Second Set of Interrogatories (July 5, 2018).

- OH-Cuyahoga, Plaintiff the County of Cuyahoga, Ohio and the State of Ohio Ex Rel. Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Second Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (Aug. 17, 2018).

- OH-Cuyahoga, Plaintiffs the County of Cuyahoga, Ohio and State of Ohio Ex Rel, Prosecuting Attorney of Cuyahoga County, Michael C. O'Malley's Amended Responses to the Manufacturer Defendants' And National Retail Pharmacy Defendants' First Set of Interrogatories and Exhibits (Nov. 2, 2018).

- OH-Cuyahoga, Manufacturer Defendants' Third Set of Interrogatories to Plaintiff County of Cuyahoga (Nov. 29, 2018).

- OH-Cuyahoga, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Supplemental Objections and Responses to Manufacturer Defendants' Interrogatory Nos. 28/29 (Dec. 28, 2018).

- OH-Cuyahoga, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Responses to Manufacturer Defendants' Third Set of Interrogatories (Dec. 31, 2018).

- OH-Cuyahoga, Manufacturer Defendants' Fourth Set of Interrogatories to Plaintiff County of Cuyahoga and Exhibit A (Jan. 19, 2019).

- OH-Cuyahoga, Manufacturer Defendants' Amended Interrogatory No. 33 to Plaintiff County of Cuyahoga (Feb. 26, 2019).

- OH-Cuyahoga, Cuyahoga County's Supplemental Response and Objections to Manufacturer Defendants' Interrogatories (Mar. 4, 2019).

- OH-Summit, Manufacturer Defendants' First Set of Requests for Production to Plaintiff City of Cleveland (Apr. 16, 2018).

- OH-Summit, Summit County, Ohio Plaintiff Entities Initial Responses and Objections to Manufacturer Defendants' First Requests for Production (May 16, 2018).

- OH-Summit, Summit County, Ohio Plaintiff Entities Amended Initial Responses and Objections to Manufacturer Defendants' First Requests for Production (May 22, 2018).

- OH-Summit, Manufacturer Defendants' Second Set of Requests for Production to Plaintiffs County of Summit and City of Akron (July 3, 2018).

- OH-Summit, County of Summit and City of Akron, Ohio Plaintiff's Responses and Objections to Manufacturer Defendants' Second Set of Requests for Production (Aug. 2, 2018).

- OH-Summit, Manufacturer Defendants' First Set of Interrogatories to Plaintiffs (Apr. 25, 2018).

- OH-Summit, Summit County, Ohio Plaintiff Entities Initial Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (May 25, 2018).

- OH-Summit, Manufacturer Defendants' Second Set of Interrogatories to Plaintiffs County of Summit and City of Akron (June 5, 2018).

- OH-Summit, Summit County, Ohio and the City of Akron, Ohio First Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (June 12, 2018).

- OH-Summit, Summit and City of Akron Plaintiff's Initial Responses and Objections to Manufacturer Defendants' Second Set of Interrogatories (July 5, 2018).

- OH-Summit, Summit County, Ohio and the City of Akron, Ohio's Second Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (Aug. 17, 2018).

- OH-Summit, Summit County, Ohio and the City of Akron, Ohio's Third Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (Oct. 8, 2018).

- OH-Summit, Summit County and the City of Akron, Ohio's Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories and Exhibits (Nov. 2, 2018).

- OH-Summit, Manufacturer Defendants' Third Set of Interrogatories to Plaintiffs County of Summit and City of Akron (Nov. 29, 2018).

- OH-Summit, Summit County, Ohio and the City of Akron, Ohio's Fourth Amended Responses and Objections to Manufacturer Defendants' First Set of Interrogatories (Dec. 14, 2018).

- OH-Summit, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Supplemental Objections and Responses to Manufacturer Defendants' Interrogatory Nos. 28/29 (Dec. 28, 2018).

- OH-Summit, Plaintiffs the City of Cleveland, County of Cuyahoga, County of Summit and City of Akron's Supplemental Amended Responses and Objections to the Manufacturer Defendants' First Set of Interrogatories, Submitted Pursuant to Discovery Ruling No. 13 (Dec. 31, 2018).

- OH-Summit, Plaintiffs Summit County, Cuyahoga County, and the Cities of Akron and Cleveland's Responses to Manufacturer Defendants' Third Set of Interrogatories (Dec. 31, 2018).

- OH-Summit, Manufacturer Defendants' Fourth Set of Interrogatories to Plaintiffs County of Summit and Akron and Exhibit A (Jan. 19, 2019).

- OH-Summit, Manufacturer Defendants' Amended Interrogatory No. 33 to Plaintiff County of Summit and City of Akron (Feb. 26, 2019).

- OH-Summit, Summit County and the City of Akron, Ohio Plaintiff's Supplemental Responses and Objections to Manufacturer Defendants' Interrogatory Numbers 1, 2, 3, 5, 8, 9, 11, 12, 13, 15, 20, 21, 26, 27, 28 & 29 (Mar. 4, 2019).

- OH-Summit, Summit County and the City of Akron, Ohio Plaintiff's Replacement Supplemental Responses and Objections to Manufacturer Defendants' Interrogatory Numbers 1, 2, 3, 5, 8, 9, 11, 12, 13, 15, 20, 21, 26, 27, 28 & 29 (Mar. 18, 2019).

VI. Produced Documents

ABDCMDL00269679
ALLERGAN_MDL_00000136
ALLERGAN_MDL_00000137
ALLERGAN_MDL_00005587
ALLERGAN_MDL_00005588
ALLERGAN_MDL_00020093

ALLERGAN_MDL_00020095
ALLERGAN_MDL_00020453
ALLERGAN_MDL_00020454
ALLERGAN_MDL_00024269
ALLERGAN_MDL_00026848
ALLERGAN_MDL_00044709
ALLERGAN_MDL_00044716
ALLERGAN_MDL_00044718
ALLERGAN_MDL_00044720
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ALLERGAN_MDL_00305287
ALLERGAN_MDL_00305294
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US-DEA-00005325
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US-DEA-00005841
US-DEA-00005911
US-DEA-00005914
US-DEA-00005918
US-DEA-00005921
US-DEA-00005925
US-DEA-00005928
US-DEA-00005949
US-DEA-00005952
US-DEA-00005958
US-DEA-00006056
US-DEA-00008563
US-DEA-00008565
US-DEA-00008577
US-DEA-00009355
US-DEA-00019479
US-DEA-00020506
US-DEA-00021243

VII. Kadian Labeling and Approval Letters

1. Kadian Label (Mar. 1, 2007)
2. Rappaport, Bob M.D. Letter from B. Rappaport, M.D. to J. Stavole re Supplemental New Drug Application dated Dec. 22, 2006 (Apr. 20, 2007).
3. Kadian Label (July 1, 2012).
4. Rappaport, Bob M.D. Letter from B. Rappaport, M.D. to T. Nataline re Supplemental New Drug Application dated Aug. 15, 2011 (July 9, 2012)
5. Rappaport, Bob M.D. Letter from B. Rappaport, M.D. to C. Salmorin re Supplemental New Drug Application dated Jan. 2, 2013 (Mar. 27, 2017).
6. Kadian Label (Apr. 1, 2014).
7. Racoosin, Judith M.D. Letter from J. Racossin to B. Byrne re Supplemental New Drug Application dated Oct. 9, 2013 (Apr. 16, 2014).
8. Highlight of Prescribing Information for Kadian (Dec. 1, 2016).
9. Hertz, Sharon M.D. Letter from S. Hertz to S. Silva re Supplemental New Drug Application dated Apr. 21, 2016 (Dec. 16, 2016).

VIII. Publications/Articles

1. 21 C.F.R. 1301.71. Security Requirements Generally (Oct. 9, 2014).
2. 21 C.F.R. 1301.74. Other Security Controls for Non-Practitioners, Narcotic Treatment Programs and Compounders for Narcotic Treatment Programs (Mar. 21, 2017).
3. 21 C.F.R. 1303. Quotas.
4. 21 C.F.R. 1304.33. Reports to Automation of Reports and Consolidated Orders System (ARCOS)(Mar. 21, 2017).
5. 21 C.F.R. Chapter 13, Drug Abuse Prevention and Control (July 24, 2018).
6. 21 C.F.R. Chapter 2, Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (July 24, 2018).

7. 21 U.S.C.A. 822. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.

8. 21 U.S.C.A. 823. Registration Requirements (Nov. 17, 2017).

9. 21 U.S.C.A. 826. Production quotas for controlled substances.

10. 21 U.S.C.A. 827. Records and Reports of Registrants (Apr. 15, 2009).

11. 21 U.S.C.A. 842. Prohibited Acts B (Dec. 18, 2014).

12. 21 U.S.C.A. 843. Prohibited Acts C (Apr. 15, 2009).

13. 21 U.S.C.A. Chapter 13, Drug Abuse Prevention and Control (July 24, 2018).

14. Anderson, Jeffrey, *Spice World* Vol. 35, No. 36 at 14 (Sept. 2015), *available at* https://www.washingtoncitypaper.com/news/article/13047146/spice-world-synthetic-drugs-have-plagued-dc-for-years-what .

15. *As new opioids spread, coroners face a wave of medical mysteries*, statnews.com (Nov. 22, 2019), *available at* https://www.statnews.com/2016/11/22/opioids-autopsies-medical-examiners/.

16. Bebinger, Martha, *Fentanyl-Linked Deaths: The U.S. Opioid Epidemic's Third Wave Begin*s, NPR (Mar. 21, 2019) ("Mar. 21, 2019 NPR Article"), *available at* https://www.npr.org/sections/health-shots/2019/03/21/704557684/fentanyl-linked-deaths-the-u-s-opioid-epidemics-third-wave-begins.

17. *Case untangles web of Chinese fentanyl sellers The overseas connection*, Plain Dealer publication (Sept. 3, 2017), Center for Disease Control & Prevention Website: Heroin Overdose Data, *available at* https://www.cdc.gov/drugoverdose/data/heroin.html..

18. Conley, Ben, *Panel discusses opioid epidemic at public forum*, The Dominion Post (Morgantown, West Virginia) (Dec. 5, 2017).

19. *Davis, Jessica, DEA partners with states to share prescription data in opioid fight, Healthcare IT News (Apr. 19, 2018), available at* https://www.healthcareitnews.com/news/dea-partners-states-share-prescription-data-opioid-fight.

20. DEA Intelligence Report*: The Opioid Threat in the Chicago Field Division* (June 2017) at 17, *available at* https://www.dea.gov/sites/default/files/2018-07/DEA-CHI-DIR-023-17%20The%20Opioid%20Threat%20in%20the%20Chicago%20FD.pdf.

21. DEA Presentation: *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conferences (2013), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/arnold.pdf).

22. DEA Presentation: *Manufacturer Trends & Updates*, Manufacturer Conference (2015), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2015/prevoznik.pdf.

23. DEA Website, DEA 360 Strategy, *available at* https://www.dea.gov/360-strategy.

24. DEA Website: Diversion Control Division, *available at* https://www.dea.gov/diversion-control-division.

25. DEA Website: Mission Statement, *available at* https://www.dea.gov/mission.

26. *DEA: U.S. Drug Enforcement Administration Emergency Schedules All Illicit Fentanyls In An Effort To Reduce Overdose Deaths* (Feb. 7, 2018), *available at* https://www.dea.gov/press-releases/2018/02/07/us-drug-enforcement-administration-emergency-schedules-all-illicit.

27. *DEA's Plea to Congress: Permanently Ban Fentanyl Substances,* Tribune Content Agency (Apr. 27, 2019), *available at* https://tribunecontentagency.com/article/deas-plea-to-congress-permanently-ban-fentanyl-substances/..

28. Department of Justice: Drug Enforcement Administration. Letter from J. Rannazzisi re Responsibilities of Controlled Substances Distributors (Feb. 7, 2007).

29. *Doctor Sentence to 5 years for Illegal Pain,* The Associated Press (May 12, 2015), *available at* https://www.wvpublic.org/post/doctor-sentenced-5-years-illegal-pain-prescriptions#stream/0.

30. *Doctor Shopping Laws,* Public Health Law, Office for State, Tribal, Local & Territorial Support, CDC (Sept. 28, 2012), *available at* https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf.

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EXHIBIT C - PRIOR TESTIMONY

I have not testified as an expert at trial or by deposition in the previous four years.